42/Pt. 400-429/988

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Public Health

42

PARTS 400 TO 429
Revised as of October 1, 1988

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42

PARTS 400 TO 429

Revised as of October 1, 1988

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AS OF OCTOBER 1, 1988

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Published by
the Office of the Federal Register
National Archives and Records
Administration

as a Special Edition of
the Federal Register

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 1988

For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402

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To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 400.200 *refers to Title 42, Part 400, section 200.*

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The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

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Title 1 through Title 16	as of January 1
Title 17 through Title 27	as of April 1
Title 28 through Title 41	as of July 1
Title 42 through Title 50	as of October 1

The appropriate revision date is printed on the cover of each volume.

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The contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507). The Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

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The Paperwork Reduction Act of 1980 (Pub. L. 96-511) requires Federal agencies to display an OMB control number with their information collection request. Many agencies have begun publishing numerous OMB control numbers as amendments to existing regulations in the CFR. These OMB numbers are placed as close as possible to the applicable recordkeeping or reporting requirements.

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(c) The incorporating document is drafted and submitted for publication in accordance with 1 CFR Part 51.

Properly approved incorporations by reference in this volume are listed in the Finding Aids at the end of this volume.

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III). A list of CFR Titles, Chapters, and Parts and an alphabetical list of agencies publishing in the CFR are also included in this volume.

An index to the text of "Title 3—The President" is carried within that volume.

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JOHN E. BYRNE,
Director,
Office of the Federal Register.

October 1, 1988.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of four volumes. The parts in these volumes are arranged in the following order: Parts 1-60, Parts 61-399, Parts 400-429 and Part 430-End. The first volume (Parts 1-60) contains current regulations issued under Chapter I—Public Health Service (HHS). The second volume (Parts 61-399) contains the remaining regulations issued under Chapter I and all current regulations issued under Chapter III—St. Elizabeths Hospital (HHS). The third volume (Parts 400-429) includes regulations issued under Chapter IV—Health Care Financing Administration (HHS) and the fourth volume (Part 430-End) contains the remaining regulations in Chapter IV and the regulations issued under Chapter V by the Office of Inspector General-Health Care (HHS). The contents of these volumes represent all current regulations codified under this title of the CFR as of October 1, 1988.

The OMB control numbers for the Health Care Financing Administration appear in § 400.310 of Chapter IV. For the convenience of the user § 400.310 is reprinted in the Finding Aids section of the fourth volume.

Redesignation tables for Chapter I—Public Health Service, Department of Health and Human Services and Chapter IV—Health Care Financing Administration, Department of Health and Human Services appear in the Finding Aids section of the second, third, and fourth volumes. A derivation table for Chapter V, Office of Inspector General Health Care appear in the third and fourth volume.

For this volume Miriam S. Braganca and Abram Primus were Chief Editors. The Code of Federal Regulations publication program is under the direction of Martha B. Girard, assisted by Ruth C. Pontius.

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Title 42—Public Health

(Parts 400 to 429)

Part

CHAPTER IV—Health Care Financing Administration, Department of Health and Human Services 400

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Editorial Note: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; and 53 FR 6634, Mar. 2, 1988.

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EDITORIAL NOTE: Chapter IV is continued in the volume containing 42 CFR Part 430 to End. For the convenience of the user, the table of contents of Chapter IV appearing in 42 CFR Part 430 to End is set forth below.

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SUBCHAPTER A—GENERAL PROVISIONS

PART 400—INTRODUCTION; DEFINITIONS

Subpart A—[Reserved]

Subpart B—Definitions

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400.200 General definitions.
400.202 Definitions specific to Medicare.
400.203 Definitions specific to Medicaid.

Subpart C—OMB Control Numbers for Approved Collections of Information

400.300 Scope.
400.310 Display of currently valid OMB control numbers.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Subpart A—[Reserved]

Subpart B—Definitions

§ 400.200 General definitions.

In this chapter, unless the context indicates otherwise—

"Act" means the Social Security Act, and titles referred to are titles of that Act.

"Administrator" means the Administrator, Health Care Financing Administration.

"Area" means the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

"CFR" stands for Code of Federal Regulations.

"Department" means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

"ESRD" stands for end-stage renal disease.

"FDA" stands for the Food and Drug Administration.

"FR" stands for *Federal Register.*

"HCFA" stands for Health Care Financing Administration.

"HHS" stands for the Department of Health and Human Services.

"HHA" stands for home health agency.

"HMO" stands for health maintenance organization.

"ICF" stands for intermediate care facility.

"Medicaid" means medical assistance provided under a State plan approved under title XIX of the Act.

"Medicare" means the health insurance program for the aged and disabled under title XVIII of the Act.

"OASDI" stands for the Old Age, Survivors, and Disability Insurance program under title II of the Act.

"PRO" stands for Utilization and Quality Control Peer Review Organization.

"Regional Administrator" means a Regional Administrator of HCFA.

"Regional Office" means one of the regional offices of HCFA.

"RHC" stands for rural health clinic.

"Secretary" means the Secretary of Health and Human Services.

"SNF" stands for skilled nursing facility.

"Social security benefits" means monthly cash benefits payable under section 202 or 223 of the Act.

"SSA" stands for Social Security Administration.

"United States" means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

"U.S.C." stands for United States Code.

"Utilization and Quality Control Peer Review Organization" (*PRO*) means an organization that has a contract with HCFA to review, under Part B of title XI of the Act, the health care services or items furnished or proposed to be furnished to Medicare beneficiaries.

[48 FR 12534, Mar. 25, 1983, as amended at 49 FR 7206, Feb. 27, 1984; 50 FR 15326 and 15358, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987]

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

"Beneficiary" means a person who is entitled to Medicare benefits.

"Carrier" means an entity that has a contract with HCFA to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

"Entitled" means that an individual meets all the requirements for Medicare benefits.

"Hospital insurance benefits" means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of title XVIII of the Act.

Intermediary" means an entity that has a contract with HCFA to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

"Medicare Part A" means the hospital insurance program authorized under Part A of title XVIII of the Act.

"Medicare Part B" means the supplementary medical insurance program authorized under Part B of title XVIII of the Act.

"Provider" means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or effective November 1, 1983 through September 30, 1986, a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

"Railroad retirement benefits" means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

"Services" means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital or SNF facilities.

"Supplementary medical insurance benefits" means payment to or on behalf of an entitled individual for services covered under Part B of title XVIII of the Act.

"Supplier" means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

[48 FR 12534, Mar. 25, 1983, as amended at 48 FR 56024, Dec. 16, 1983; 49 FR 3658, Jan. 30, 1984; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987]

§ 400.203 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

"Applicant" means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

"Federal financial participation" (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

"FMAP" stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

"Medicaid agency" or *"agency"* means the single State agency administering or supervising the administration of a State Medicaid plan.

"Provider" means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

"Recipient" means an individual who has been determined eligible for Medicaid.

"Services" means the types of medical assistance specified in sections 1905(a)(1) through (18) of the Act.

"State" means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

"State plan" or *"the plan"* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administra-

tion of a Medicaid program in accordance with Federal requirements.

[48 FR 12534, Mar. 25, 1983, as amended at 50 FR 33029, Aug. 16, 1985]

Subpart C—OMB Control Numbers for Approved Collections of Information

SOURCE: 49 FR 4477, Feb. 7, 1984, unless otherwise noted.

§ 400.300 Scope.

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in HCFA regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR Part 1320. HCFA intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. Chapter 35 which requires that agencies shall not engage in a "collection of information" without obtaining a control number from OMB.

§ 400.310 Display of currently valid OMB control numbers.

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403.232, 403.239–403.258	0938–0264
403.304, 403.306, 403.312, 403.316, 403.318 and 403.320–403.322	0938–0473
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498.22, 498.40, 498.58, 498.82	0938–0508

[53 FR 16268, May 6, 1988; 53 FR 21762, June 9, 1988, as amended at 53 FR 36571, Sept. 21, 1988]

Effective Date Note: At 53 FR 36571, Sept. 21, 1988, § 400.310 was amended by adding "430.30" and its corresponding OMB control numbers "0938-0067" and "0938-0101" to the table, effective October 21, 1988.

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

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Subpart B—Confidentiality and Disclosure

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401.102 Definitions.
401.105 Rules for disclosure.
401.106 Publication.
401.108 HCFA Rulings.
401.110 Publications for sale.
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Subpart F—Claims Collection and Compromise

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401.603 Definitions.
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Subpart A—[Reserved]

Subpart B—Confidentiality and Disclosure

Authority: Secs. 205, 1102, 1106, and 1871 of the Social Security Act (42 U.S.C. 405, 1302, 1306, and 1395hh); the Freedom of Information Act (5 U.S.C. 552); and the Privacy Act (5 U.S.C. 552a).

Source: 46 FR 55696, Nov. 12, 1981, unless otherwise noted.

§ 401.101 Purpose and scope.

(a) The regulations in this subpart (1) Implement section 1106(a) of the Social Security Act as it applies to the Health Care Financing Administration (HCFA). The rules apply to information obtained by officers or employees of HCFA in the course of administering title XVIII of the Social Security Act (Medicare), information obtained by Medicare intermediaries or carriers in the course of carrying out agreements under sections 1816 and 1842 of the Social Security Act, and any other information subject to section 1106(a) of the Social Security Act;

(2) Relate to the availability to the public, under 5 U.S.C. 552, of records of HCFA and its components. They set out what records are available and how they may be obtained; and

(3) Supplement the regulations of the Department of Health and Human Services relating to availability of information under 5 U.S.C. 552, codified in 45 CFR Part 5, and do not replace or restrict them.

(b) Except as authorized by the rules in this subpart, no information described in paragraph (a)(1) of this section shall be disclosed. The procedural rules in this subpart (§§ 401.106 through 401.152) shall be applied to requests for information which is subject to the rules for disclosure in this subpart.

(c) Requests for information which may not be disclosed according to the provisions of this subpart shall be denied under authority of section 1106(a) of the Social Security Act and this subpart, and furthermore, such requests which have been made pursuant to the Freedom of Information Act shall be denied under authority of an appropriate Freedom of Information Act exemption, 5 U.S.C. 552(b).

§ 401.102 Definitions.

For purposes of this subpart: "Act" means the Social Security Act.

"Freedom of Information Act rules" means the substantive mandatory disclosure provisions of the Freedom of Information Act, 5 U.S.C. 552 (including the exemptions from mandatory disclosure, 5 U.S.C. 552(b), as implemented by the Department's public information regulation, 45 CFR Part 5, Subpart F and by §§ 401.106 to 401.152 of this subpart.

"Person" means a person as defined in the Administrative Procedure Act, 5 U.S.C. 551(2). This includes State or local agencies, but does not include Federal agencies or State or Federal courts.

"Record" has the same meaning as that provided in 45 CFR 5.5.

"Subject individual" means an individual whose record is maintained by the Department in a system of records, as the terms "individual," "record", and "system of records" are defined in the Privacy Act of 1974, 5 U.S.C. 552a(a).

§ 401.105 Rules for disclosure.

(a) *General rule.* The Freedom of Information Act rules shall be applied to every proposed disclosure of information. If, considering the circumstances of the disclosure, the information would be made available in accordance with the Freedom of Information Act rules, then the information may be disclosed regardless of whether the requester or recipient of the information has a statutory right to request the information under the Freedom of Information Act, 5 U.S.C. 552, or whether a request has been made.

(b) *Application of the general rule.* Pursuant to the general rule in paragraph (a) of this section,

(1) Information shall be disclosed—

(i) To a subject individual when required by the access provision of the Privacy Act, 5 U.S.C. 552a(d), as implemented by the Department Privacy Act regulation, 45 CFR Part 5b; and

(ii) To a person upon request when required by the Freedom of Information Act, 5 U.S.C. 552;

(2) Unless prohibited by any other statute (e.g., the Privacy Act of 1974, 5 U.S.C. 552a(b), the Tax Reform Act of 1976, 26 U.S.C. 6103, or section 1106(d) and (e) of the Social Security Act), information may be disclosed to any requester or recipient of the information, including another Federal agency or a State or Federal court, when the information would not be exempt from mandatory disclosure under Freedom of Information Act rules or when the information nevertheless would be made available under the Department's public information regulation's criteria for disclosures which are in the public interest and consistent with obligations of confidentiality and administrative necessity, 45 CFR Part 5, Subpart F, as supplemented by §§ 401.106 to 401.152 of this subpart.

[42 FR 14704, Mar. 16, 1977. Redesignated at 45 FR 74913, 74914, Nov. 13, 1980, and correctly redesignated at 46 FR 24551, May 1, 1981, and amended at 46 FR 55697, Nov. 12, 1981]

§ 401.106 Publication.

(a) *Methods of publication.* Materials required to be published under the provisions of The Freedom of Information Act, 5 U.S.C. 552 (a)(1) and (2) are published in one of the following ways:

(1) By publication in the FEDERAL REGISTER of HCFA regulations, and by their subsequent inclusion in the Code of Federal Regulations;

(2) By publication in the FEDERAL REGISTER of appropriate general notices;

(3) By other forms of publication, when incorporated by reference in the FEDERAL REGISTER with the approval of the Director of the Federal Register; and

(4) By publication of indexes of precedential orders and opinions issued in the adjudication of claims, statements of policy and interpretations which have been adopted but have not been published in the FEDERAL REGISTER, and of administrative staff manuals and instructions to staff that affect a member of the public.

(b) *Availability for inspection.* Those materials which are published in the FEDERAL REGISTER pursuant to 5 U.S.C. 552(a)(1) shall, to the extent practicable and to further assist the public, be made available for inspection at the places specified in § 401.128.

[46 FR 55696, Nov. 12, 1981, as amended at 48 FR 22924, May 23, 1983]

§ 401.108 HCFA Rulings.

(a) After September 1981, a precedent final opinion or order or a statement of policy or interpretation that has not been published in the FEDERAL REGISTER as a part of a regulation or of a notice implementing regulations, but which has been adopted by HCFA as having precedent, may be published in the FEDERAL REGISTER as a HCFA Ruling and will be made available in the publication entitled *HCFA Rulings.*

(b) Precedent final opinions and orders and statements of policy and interpretation that were adopted by HCFA before October, 1981, and that have not been published in the FEDERAL REGISTER are available in *HCFA Rulings.*

(c) HCFA Rulings are published under the authority of the Administrator, HCFA. They are binding on all HCFA Components, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of HCFA.

[48 FR 22924, May 23, 1983]

§ 401.110 Publications for sale.

The following publications containing information pertaining to the program, organization, functions, and procedures of HCFA may be purchased from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

(a) Titles 20, 42, and 45 of the Code of Federal Regulations.

(b) FEDERAL REGISTER issues.

(c) Compilation of the Social Security Laws.

(d) HCFA Rulings.

(e) Social Security Handbook. The information in the Handbook is not of precedent or interpretative force.

(f) Medicare/Medicaid Directory of Medical Facilities.

§ 401.112 Availability of administrative staff manuals.

All HCFA administrative staff manuals and instructions to staff personnel which contain policies, procedures, or interpretations that affect the public are available for inspection and copying. A complete listing of such materials is published in HCFA Rulings. These manuals are generally not printed in a sufficient quantity to permit sale or other general distribution to the public. Selected material is maintained at Social Security Administration district offices and field offices and may be inspected there. See §§ 401.130 and 401.132 for a listing of this material.

§ 401.116 Availability of records upon request.

(a) *General.* In addition to the records made available pursuant to §§ 401.106, 401.108, 401.110 and 401.112, HCFA will, upon request made in accordance with this subpart, make identified records available to any person, unless they are exempt from disclosure under the provisions of section 552(b) of Title 5, United States Code (see § 401.126), or any other provision of law.

(b) *Misappropriation, alteration, or destruction of records.* No person may remove any record made available to him for inspection or copying under this part, from the place where it is made available. In addition, no person may steal, alter, mutilate, obliterate, or destroy in whole or in part, such a record. See sections 641 and 2071 of title 18 of the United States Code.

§ 401.118 Deletion of identifying details.

When HCFA publishes or otherwise makes available an opinion or order, statement of policy, or other record which relates to a private party or parties, the name or names or other identifying details will be deleted.

§ 401.120 Creation of records.

Records will not be created by compiling selected items from the files, and records will not be created to provide the requester with such data as ratios, proportions, percentages, per capitas, frequency distributions, trends, correlations, and comparisons. If such data have been compiled and are available in the form of a record, the record shall be made available as provided in this subpart.

§ 401.126 Information or records that are not available.

(a) *Specific exemptions from disclosure.* Pursuant to paragraph (b) of 5 U.S.C. 552, certain classes of records are exempt from disclosure. For some examples of the kinds of materials which are exempt, see Subpart F of the public information regulation of the Department of Health and Human Services (45 CFR Part 5) and the appendix to that regulation.

(b) *Materials exempt from disclosure by statute.* Pursuant to paragraph (b)(3) of 5 U.S.C. 552, as amended, which exempts from the requirement for disclosure matters that are exempted from disclosure by statute, provided that such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or establishes particular criteria for withholding or refers to particular types of matter to be withheld:

(1) Reports described in sections 1106 (d) and (e) of the Social Security Act shall not be disclosed, except in accordance with the provisions of sections 1106 (d) and (e). Sections 1106 (d) and (e) provide for public inspection of certain official reports dealing with the operation of the health programs established by titles XVIII and XIX of the Social Security Act (Medicare and Medicaid), but require that program validation survey reports and other formal evaluations of providers of services shall not identify individual patients, individual health care practitioners, or other individuals. Section 1106(e) further requires that none of the reports shall be made public until the contractor or provider whose performance is being evaluated has had a reasonable opportunity to review that report and to offer comments. See § 401.133 (b) and (c);

(2) Disclosure of materials described in section 1865(a)(2) of the Social Security Act as amended, is prohibited. Section 1865(a)(2) provides for release by the Joint Commission on the Accreditation of Hospitals (JCAH) to the Secretary (or a State agency designated by him) on a confidential basis accreditation surveys made by JCAH, if the hospitals authorize such release. Materials which are confidential under this provision include accreditation letters and accompanying Recommendations and Comments prepared by the JCAH concerning hospitals surveyed by it; and

(3) Tax returns and return information defined in section 6103 of the Internal Revenue Code, as amended by the Tax Reform Act of 1976, shall not be disclosed except as authorized by the Internal Revenue Code.

(c) *Effect of exemption.* Neither 5 U.S.C. 552 nor this regulation directs the withholding of any record or information, except to the extent of the prohibitions in paragraph (b) of this section. Except for material required to be withheld under the statutory provisions incorporated in paragraph (b) of this section or under another statute which meets the standards in 5

U.S.C. 552(b)(3), materials exempt from mandatory disclosure will nevertheless be made available when this can be done consistently with obligations of confidentiality and administrative necessity. The disclosure of materials or records under these circumstances in response to a specific request, however, is of no precedent force with respect to any other request.

§ 401.128 Where requests for records may be made.

(a) *General.* Any request for any record may be made to—

(1) Any HCFA component;

(2) Director, Office of Public Affairs, HCFA 313-H, Hubert H. Humphrey Building, 200 Independence Avenue, Washington, D.C. 20201; or

(3) Director of Public Affairs in any Regional Office of the Department of Health and Human Services.

The locations and service areas of these offices are as follows:

Region I—John F. Kennedy Federal Building, Boston, MA 02203. Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.
Region II—26 Federal Plaza, New York, NY 10007. New York, New Jersey, Puerto Rico, Virgin Islands.
Region III—Gateway Building, 3535 Market Street, Philadelphia, PA 19101. Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia.
Region IV—101 Marietta Street, Altanta, GA 30323. Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.
Region V—300 South Wacker Drive, Chicago, IL 60606. Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin.
Region VI—1200 Main Tower Building, Dallas, TX 75202. Arkansas, Louisiana, New Mexico, Oklahoma, Texas.
Region VII—601 East 12th Street, Kansas City, MO 64106. Iowa, Kansas, Missouri, Nebraska.
Region VIII—Federal Office Building, 19th and Stout Streets, Denver, CO 80294. Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming.
Region IX—Federal Office Building, 50 United Nations Plaza, San Francisco, CA 94102. Arizona, California, Hawaii, Nevada, Guam, Trust Territory of Pacific Islands, American Samoa.
Region X—Arcade Plaza Building, 1321 Second Avenue, Seattle, WA 98101. Alaska, Idaho, Oregon, Washington.

(b) *Records pertaining to individuals.* HCFA maintains some records pertaining to individuals. Disclosure of such records is generally prohibited by section 1106 of the Social Security Act (42 U.S.C. 1306), except as prescribed in § 401.105 (See also § 401.126(b)). Requests for records pertaining to individuals may be addressed to:

Director, Office of Research, Demonstrations and Statistics, HCFA, Baltimore, Maryland 21235, when information is sought from the record of a person who has participated in a research survey conducted by or for HCFA, Office of Research, Demonstrations and Statistics; or whose records have been included by statistical sampling techniques in research and statistical studies authorized by the Social Security Act in the field of health care financing.

(c) *Requests for materials listed in § 401.130 or § 401.132 or indexed in the HCFA Rulings.* A request to inspect and copy materials listed in § 401.130 or § 401.132 or indexed in HCFA Rulings may be made to any district or branch office of the Social Security Administration. If the specific material requested is not available in the office receiving the request, the material will be obtained and made available promptly.

§ 401.130 Materials available at social security district offices and branch offices.

(a) *Materials available for inspection.* The following are available or will be made available for inspection at the social security district offices and branch offices:

(1) Compilation of the Social Security Laws.

(2) The Public Information Regulation of the Department of Health and Human Services (45 CFR Part 5).

(3) Medicare Program regulations issued by the Health Care Financing Administration. 42 CFR Chapter IV .

(4) HCFA Rulings.

(5) Social Security Handbook.

(b) *Materials available for inspection and copying.* The following materials are available or will be made available for inspection and copying at the social security district offices and branch offices:

(1) Claims Manual of the Social Security Administration.

(2) Department Staff Manual on Organization, Department of Health and Human Services, Part F, HCFA.

(3) Parts 2 and 3 of the Part A Intermediary Manual (Provider Services under Medicare HCFA Pub. 13-2 and 13-3).

(4) Parts 2 and 3 of the Part B Intermediary Manual (Physician and Supplier Services).

(5) Intermediary Letters Related to Parts 2 and 3 of the Part A and Part B Intermediary Manuals.

(6) State Buy-In Handbook (State Enrollment of Eligible Individuals under the Supplementary Medical Insurance Program) and Letters.

(7) Group Practice Prepayment Plan Manual (HIM-8) and Letters.

(8) State Operations Manual (HIM-7).

(9) HCFA Letters to State Agencies on Medicare.

(10) Skilled Nursing Facility Manual (HCFA Pub. 12).

(11) Hearing Officers Handbook (Supplementary Medical Insurance Program—HIM-21).

(12) Hospital Manual (HIM-10).

(13) Home Health Agency Manual (HIM-11).

(14) Outpatient Physical Therapy Provider Manual (HIM-9).

(15) Provider Reimbursement Manual (HIM-15).

(16) Audit Program Manuals for Hospital (HIM-16), Home Health Agency (HIM-17), and Extended Care Facilities (HIM-18).

(17) Statements of deficiencies based upon survey reports of health care institutions or facilities prepared after January 31, 1973, by a State agency, and such reports (including pertinent written statements furnished by such institution or facility on such statements of deficiencies), as set forth in § 401.133(a). Such statements of deficiencies, reports, and pertinent written statements shall be available or made available only at the social security district office and regional office servicing the area in which the institution or facility is located, except that such statements of deficiencies and pertinent written statements shall also be available at the local public assistance offices servicing such area.

(18) Indexes to the materials listed in paragraph (a) of this section and in this paragraph (b) and an index to the Bureau of Hearings and Appeals Handbook.

§ 401.132 Materials in field offices of the Office of Hearings and Appeals, SSA.

(a) *Materials available for inspection.* The following materials are available for inspection in the field offices of the Office of Hearings and Appeals, SSA.

(1) Title 45 of the Code of Federal Regulations (including the public information regulation of the Department of Health and Human Services).

(2) Regulations of the Social Security Administration and HCFA.

(3) Title 5, United States Code.

(4) Compilation of the Social Security Laws.

(5) HCFA Rulings.

(6) Social Security Handbook.

(b) *Handbook available for inspection and copying.* The Office of Hearings and Appeals Handbook is available for inspection and copying in the field offices of the Office of Hearings and Appeals.

§ 401.133 Availability of official reports on providers of services, State agencies, intermediaries, and carriers under Medicare.

The following shall be made available to the public under the conditions specified:

(a) *Statements of deficiencies and survey reports on providers of services prepared by State agencies.* (1) Statements of deficiencies based upon official survey reports prepared after January 31, 1973, by a State agency pursuant to its agreement entered into under section 1864 of the Social Security Act and furnished to HCFA, which relate to a State agency's findings on the compliance of a health care institution or facility with the applicable provisions in section 1861 of the Act and with the regulations, promulgated pursuant to those provisions, dealing with health and safety of patients in those institutions and facilities; and (2) State agency survey reports. The statement of deficiencies or report and any pertinent written statements furnished by the institution or facility on the statement of deficiencies shall be disclosed within 90 days following the completion of the survey by the State agency, but not to exceed 30 days following the receipt of the report by HCFA. (See § 401.130(b)(17)) for places where statements of deficiencies, reports, and pertinent written statements will be available.)

(b) *HCFA reports on providers of services.* Upon request in writing, official reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the performance of providers of services under Medicare: *Provided,* That no information identifying individual patients, physicians, or other practitioners, or other individuals shall be disclosed under this paragraph. Those reports and other evaluations shall be disclosed within 30 days following the final preparation thereof by HCFA during which time the providers of services shall be afforded a reasonable opportunity to offer comments, and there shall be disclosed with those reports and evaluations any pertinent written statements furnished HCFA by those providers on those reports and evaluations.

(c) *Contractor performance review reports.* Upon request in writing, official contractor performance review reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the evaluation of the performance of (1) intermediaries and carriers under their agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act and (2) State agencies under their agreements entered into pursuant to section 1864 of the Act (including comparative evaluations of the performance of those intermediaries, carriers, and State agencies). The latest Contract Performance Review Report pertaining to a particular intermediary or carrier, prepared prior to February 1, 1973, may also be disclosed to any person upon request in writing. Those reports and evaluations shall be disclosed within 30 days following their final preparation by HCFA (or 30 days following the request therefor, in the case of the contract performance review report prepared prior to February 1, 1973), during which time those intermediaries, carriers, and State agencies, as the case may be, shall be afforded a reasonable opportunity to offer comments, and there shall be disclosed with those reports and evaluations any pertinent written statements furnished HCFA by those intermediaries, carriers, on State agencies or those reports and evaluations.

[46 FR 55696, Nov. 12, 1981; 46 FR 59249, Dec. 4, 1981]

§ 401.134 Release of Medicare information to State and Federal agencies.

(a) Except as provided in paragraph (b) of this section, the following information may be released to an officer or employee of an agency of the Federal or a State government lawfully charged with the administration of a program receiving grants-in-aid under title V and XIX of the Social Security Act for the purpose of administration of those titles, or to any officer or employee of the Department of Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS):

(1) Information, including the identification number, concerning charges made by physicians, other practitioners, or suppliers, and amounts paid under Medicare for services furnished to beneficiaries by such physicians, other practioners, or suppliers, to enable the agency to determine the proper amount of benefits payable for medical services performed in accordance with those programs; or

(2) Information as to physicians or other practioners that has been disclosed under § 401.105.

(3) Information relating to the qualifications and certification status of hospitals and other health care facilities obtained in the process of determining whether, and certifying as to whether, institutions or agencies meet or continue to meet the conditions of participation of providers of services or whether other entities meet or continue to meet the conditions for coverage of services they furnish.

(b) The release of such information shall not be authorized by a fiscal intermediary or carrier.

(c) The following information may be released to any officer or employee of an agency of the Federal or a State government lawfully charged with the duty of conducting an investigation or prosecution with respect to possible fraud or abuse against a program receiving grants-in-aid under Medicaid, but only for the purpose of conducting such an investigation or prosecution, or to any officer or employee of the Department of the Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), provided that the agency has filed an agreement with HCFA that the information will be released only to the agency's enforcement branch and that the agency will preserve the confidentiality of the information received and will not disclose that information for other than program purposes:

(1) The name and address of any provider of medical services, organization, or other person being actively investigated for possible fraud in connection with Medicare, and the nature of such suspected fraud. An active investigation exists when there is significant evidence supporting an initial complaint but there is need for further investigation.

(2) The name and address of any provider of medical services, organization, or other person found, after consultation with an appropriate professional association or a program review team, to have provided unnecessary services, or of any physician or other individual found to have violated the assignment agreement on at least three occasions.

(3) The name and address of any provider of medical services, organization or other person released under paragraph (c)(1) or (2) of this section concerning which an active investigation is concluded with a finding that there is no fraud or other prosecutable offense.

§ 401.135 Release of Medicare information to the public.

The following shall be made available to the public under the conditions specified:

(a) Information as to amounts paid to providers and other organizations and facilities for services to beneficiaries under title XVIII of the Act: *Provided*, That no information identifying any particular beneficiaries shall be disclosed under this paragraph.

(b) The name of any provider of services or other person furnishing services to Medicare beneficiaries who—

(1) Has been found by a Federal court to have been guilty of submitting false claims in connection with Medicare; or

(2) Has been found by a carrier or intermediary, after consultation with a professional medical association functioning external to program administration or, if appropriate, the State medical authority, to have been engaged in a pattern of furnishing services to beneficiaries which are substantially in excess of their medical needs; except that the name of any provider or other person shall not be disclosed pursuant to a finding under this paragraph (b)(2) of this section, unless that provider or other person has first been afforded a reasonable opportunity to offer evidence on his behalf.

(c) Upon request in writing, cost reports submitted by providers of services pursuant to section 1815 of the Act to enable the Secretary to determine amounts due the providers.

§ 401.136 Requests for information or records.

(a) A request should reasonably identify the requested record by brief description. Requesters who have detailed information which would assist in identifying the records requested are urged to provide such information in order to expedite the handling of the request. Envelopes in which written requests are submitted should be clearly identified as Freedom of Information requests. The request should include the fee or request determination of the fee. When necessary, a written request will be promptly forwarded to the proper office, and the requester will be advised of the date of the receipt and identification and address of the proper office.

(b) Determinations of whether records will be released or withheld will be made within 10 working days from date of receipt of the request in the office listed in § 401.128 except where HCFA extends this time and sends notice of such extension to the requester. Such extension may not exceed 10 additional working days and shall apply only where the following unusual circumstances exist:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the requests;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are requested in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the request or among two or more components of HCFA having a substantial interest in the subject matter of the request.

(c) If an extension is made, the requester will be notified in writing before the expiration of 10 working days from receipt of the request and will be given an explanation of why the extension was necessary and the date on which a determination will be made.

(d) Authority to extend the time limit with respect to any request for information or records is granted to the Director, Office of Public Affairs, HCFA and to the Director of Public Affairs in any HHS Regional Office. Those officers and employees of HCFA who are listed in § 401.144(a) as having authority to deny requests for information from records maintained on individuals are granted authority to extend the time limit for responding to requests for information from such records.

§ 401.140 Fees and charges.

(a) *Statement of policy.* It is HCFA's policy to comply with certain requests for information services without charge. Except as otherwise determined pursuant to paragraph (c) of this section, fees will be charged for the following services with respect to all other requests for information from records which are reasonably identified by the requesters:

(1) Reproduction, duplication, or copying of records;

(2) Searches for records; and

(3) Certification or authentication of records.

(b) *Fee schedules.* The fee schedule is as follows:

(1) *Search for records.* Three dollars per hour: *Provided, however,* That no charge will be made for the first half hour.

(2) *Reproduction, duplication, or copying of records.* Ten cents per page where such reproduction can be made by commonly available photocopying machines. The cost of reproducing records which cannot be so photocopied will be determined on an individual basis at actual cost.

(3) *Certification or authentication of records.* Three dollars per certification or authentication.

(4) *Forwarding materials to destination.* Any special arrangements for forwarding which are requested shall be charged at actual cost; however, no charge will be made for postage.

(5) No charge will be made when the total amount does not exceed five dollars.

(c) *Waiver or reduction of fees.* Waiver or reduction of the fees in paragraph (b) of this section may be made upon a determination that such waiver or reduction is in the public interest because furnishing the information can be considered as primarily benefiting the general public. Such determination may be made by the appropriate officer or employee identified in § 401.144.

(d) *Sale of documents.* On occasion, a previously printed document may be available for sale to the public; the cost of supplying the document is one cent per page unless the document is available for sale from the Superintendent of Documents, in which case the price shall be that determined by the Superintendent.

§ 401.144 Denial of requests.

(a) *General authority.* Only the Director, Office of Public Affairs, HCFA, and the Regional Directors of Public Affairs, HHS, are authorized to deny written requests to obtain, inspect or copy any HCFA information or record.

(b) *Forms of denials.* (1) Oral requests may be dealt with orally, but the requester should be advised that the oral response is not an official determination and that an official determination may be obtained only by submitting the request in writing. Appropriate available assistance will be offered.

(2) Written Requests—Denials of written requests will be in writing and will contain the reasons for the denial including, as appropriate, a statement that a document requested is nonexistent or not reasonably described or is subject to one or more clearly described exemption(s). Denials will also provide the requester with appropriate information on how to exercise the right of appeal.

§ 401.148 Administrative review.

(a) *Review by the Administrator.* A person whose request has been denied may initiate a review by filing a request for review with the Administrator of HCFA, 700 East High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235, within 30 days of receipt of the determination to deny or within 30 days of receipt of records which are in partial response to his request if a portion of a request is granted and a portion denied, whichever is later. Upon receipt of a timely request for review, the Administrator will review the decision in question and the findings upon which it was based. Upon the basis of the data considered in connection with the decision and whatever other evidence and written argument is submitted by the person requesting the review or which is otherwise obtained, the Administrator or his designee will affirm or revise in whole or in part the findings and decision in question. A decision to affirm the denial will be made only upon concurrence of the Assistant Secretary for Public Affairs, or his designee, after consultation with the General Counsel or his or her designee, and the appropriate program policy official. Written notice of the decision of the Administrator will be mailed to the person who requested the review. A written decision will be made within 20 working days from receipt of the request for review. Extension of the time limit may be granted under the circumstances listed in § 401.136(b) to the extent that the maximum 10 days limit on extensions has not been exhausted on the initial determination. The decision will include the basis for it and will advise the requester of his right to judicial review.

(b) *Failure of the Administrator to comply with the time limits.* Failure of the Administrator to comply with the time limits set forth in § 401.136 and this section constitutes an exhaustion of the requester's administrative remedies.

§ 401.152 Court review.

Where the Administrator upon review affirms the denial of a request for records, in whole or in part, the requester may seek court review in the district court of the United States pursuant to 5 U.S.C. 552(a)(4)(B).

Subparts C–E—[Reserved]

Subpart F—Claims Collection and Compromise

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 31 U.S.C. 3711.

SOURCE: 48 FR 39064, Aug. 29, 1983, unless otherwise noted.

§ 401.601 Basis and scope.

(a) *Basis.* This subpart implements for HCFA the Federal Claims Collection Act (FCCA) of 1966 (31 U.S.C. 3711), and conforms to the regulations

(4 CFR Parts 101-105) issued jointly by the General Accounting Office and the Department of Justice that generally prescribe claims collection standards and procedures under the FCCA for the Federal government.

(b) *Scope.* Except as provided in paragraphs (c) through (f) of this section, the regulations in this subpart describe HCFA's procedures and standards for the collection of claims in any amount, and the compromise of, or the suspension or termination of collection action on , all claims for money or property that do not exceed $20,000 exclusive of interest, arising under any functions delegated to HCFA by the Secretary.

(c) *Amount of claim.* HCFA refers all claims that exceed $20,000, exclusive of interest, to the Department of Justice or the General Accounting Office for the compromise of claims, or the suspension or termination of collection action.

(d) *Related regulations*—(1) *Department regulations.* DHHS regulations applicable to HCFA that generally implement the FCCA for the Department are located at 45 CFR Part 30.

(2) *HCFA regulations.* The following regulations govern specific debt management situations encountered by HCFA and supplement this subpart:

(i) Claims against Medicare beneficiaries for the recovery of overpayments are covered in 20 CFR 404.515.

(ii) Adjustments in Railroad Retirement or Social Security benefits to recover Medicare overpayments to individuals are covered in §§ 405.350–405.356 of this chapter.

(iii) Claims against providers, physicians, or other suppliers of services for overpayments under Medicare and for assessment of interest are covered in §§ 405.374 and 405.376 of this chapter, respectively.

(iv) Claims against beneficiaries for unpaid hospital insurance or supplementary medical insurance premiums under Medicare are covered in § 408.110 of this chapter.

(v) State repayment of Medicaid funds by installments is covered in § 430.48 of this chapter.

(e) *Collection and compromise under other statutes and at common law.* The regulations in this subpart do not—

(1) Preclude disposition by HCFA of claims under statutes, other than the FCCA, that provide for the collection or compromise of a claim, or suspension or termination of collection action.

(2) Affect any rights that HCFA may have under common law as a creditor.

(f) *Fraud.* The regulations in this subpart do not apply to claims in which there is an indication of fraud, the presentation of a false claim, or misrepresentation on the part of a debtor or any other party having an interest in the claim. HCFA forwards these claims to the Department of Justice for disposition under 4 CFR 105.1.

(g) *Enforced collection.* HCFA refers claims to the Department of Justice for enforced collection through litigation in those cases which cannot be compromised or on which collection action cannot be suspended or terminated in accordance with this subpart or the regulations issued jointly by the Attorney General and the Comptroller General.

[48 FR 39064, Aug. 29, 1983, as amended at 52 FR 48123, Dec. 18, 1987]

§ 401.603 Definitions.

For purposes of this subpart—

Claim means any debt owed to HCFA.

Debtor means any individual, partnership, corporation, estate, trust or other legal entity against which HCFA has a claim.

§ 401.605 Omissions not a defense.

The failure of HCFA to comply with the regulations in this subpart, or with the related regulations listed in § 401.601(d), is not available as a defense to a debtor against whom HCFA has a claim for money or property.

§ 401.607 Claims collection.

(a) *General policy.* HCFA recovers amounts of claims due from debtors, including interest where appropriate, by—

(1) Direct collections in lump sums or in installments; or

(2) Offsets against monies owed to the debtor by the Federal government where possible.

(b) *Collection in lump sums.* Whenever possible, HCFA attempts to collect claims in full in one lump sum. However, if HCFA determines that a debtor is unable to pay the claim in one lump sum, HCFA may instead enter into an agreement to accept regular installment payments.

(c) *Collection in installments.* Generally, HCFA requires that all claims to be satisfied by installment payments must be liquidated in three years or less. If unusual circumstances exist, such as the possibility of debtor insolvency, an installment agreement that extends beyond three years may be approved.

(1) *Debtor request.* If a debtor desires to repay a claim in installments, the debtor must submit—

(i) A request to HCFA; and

(ii) Any information required by HCFA to make a decision regarding the request.

(2) *HCFA decision.* HCFA will determine the number, amount and frequency of installment payments based on the information submitted by the debtor and on other factors such as—

(i) Total amount of the claim;

(ii) Debtor's ability to pay; and

(iii) Cost to HCFA of administering an installment agreement.

(d) *Collection by offset.* (1) In conformity with 4 CFR 102.3, HCFA may offset, where possible, the amount of a claim against the amount of pay, compensation, benefits or other monies that a debtor is receiving or is due from the Federal government.

(2) Under regulations at §§ 405.350-405.356 of this chapter, HCFA may initiate adjustments in program payments to which an individual is entitled under title II of the Act (Federal Old Age, Survivors, and Disability Insurance Benefits) or under the Railroad Retirement Act of 1974 (45 U.S.C. 231) to recover Medicare overpayments.

§ 401.613 Compromise of claims.

(a) *Amount of compromise.* HFCA requires that the amount to be recovered through a compromise of a claim must—

(1) Bear a reasonable relation to the amount of the claim; and

(2) Be recoverable through enforced collection procedures.

(b) *General factors.* After considering the bases for a decision to compromise a claim under paragraph (c) of this section, HCFA may further consider factors such as—

(1) The age and health of the debtor if the debtor is an individual;

(2) Present and potential income of the debtor; and

(3) Whether assets have been concealed or improperly transferred by the debtor.

(c) *Basis for compromise.* Bases on which HCFA may compromise a claim include the following—

(1) *Inability to pay.* HCFA may compromise a claim if it determines that the debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount of the claim within a reasonable time.

(2) *Litigative probabilities.* HCFA may compromise a claim if it determines that it would be difficult to prevail in a case before a court of law as a result of the legal issues involved or inability of the parties to agree to the facts of the case. The amount that HCFA accepts in compromise under this provision will reflect—

(i) The likelihood that HCFA would have prevailed on the legal question(s) involved;

(ii) Whether and to what extent HCFA would have obtained a full or partial recovery of a judgment, depending on the availability of witnesses, or other evidentiary support for HCFA's claim; and

(iii) The amount of court costs that would be assessed to HCFA.

(3) *Cost of collecting the claim.* HCFA may compromise a claim if it determines that the cost of collecting the claim does not justify the enforced collection of the full amount. In this case, HCFA may adjust the amount it accepts as a compromise to allow an appropriate discount for the costs of collection it would have incurred but for the compromise.

(d) *Enforcement policy.* HCFA may compromise statutory penalties, forfeitures, or debts established as an aid to enforcement or to compel compliance, if it determines that its enforcement policy, in terms of deterrence and securing compliance both present and future, is adequately served by acceptance of the compromise amount.

§ 401.615 Payment of compromise amount.

(a) *Time and manner of compromise.* Payment by the debtor of the amount that HCFA has agreed to accept as a compromise in full settlement of a claim must be made within the time and in the manner prescribed by HCFA. Accordingly, HCFA will not settle a claim until the full payment of the compromise amount has been made.

(b) *Effect of failure to pay compromise amount.* Failure of the debtor to make payment, as provided by the compromise agreement, reinstates the full amount of the claim, less any amounts paid prior to the default.

(c) *Prohibition against grace periods.* HCFA will not agree to inclusion of a provision in an installment agreement that would permit grace periods for payments that are late under the terms of the agreement.

§ 401.617 Suspension of collection action.

(a) *General conditions.* HCFA may temporarily suspend collection action on a claim if the following general conditions are met—

(1) *Amount of future recovery.* HCFA determines that future collection action may result in a recovery of an amount sufficient to justify periodic review and action on the claim by HCFA during the period of suspension.

(2) *Statute of limitations.* HCFA determines that—

(i) The applicable statute of limitations has been tolled, waived or has started running anew; or

(ii) Future collections may be made by HCFA through offset despite an applicable statute of limitations.

(b) *Basis for suspension.* Bases on which HCFA may suspend collection action on a particular claim include the following—

(1) A debtor cannot be located; or

(2) A debtor—

(i) Owns no substantial equity in property;

(ii) Is unable to make payment on HCFA's claim or is unable to effect a compromise; and

(iii) Has future prospects that justify retention of the claim.

(c) *Locating debtors.* HCFA will make every reasonable effort to locate missing debtors sufficiently in advance of the bar of an applicable statute of limitations to permit timely filing of a lawsuit to recover the amount of the claim.

(d) *Effect of suspension on liquidation of security.* HCFA will liquidate security, obtained in partial recovery of a claim, despite a decision under this section to suspend collection action against the debtor for the remainder of the claim.

§ 401.621 Termination of collection action.

(a) *General factors.* After considering the bases for a decision to terminate collection action under paragraph (b) of this section, HCFA may further consider factors such as—

(1) The age and health of the debtor if the debtor is an individual;

(2) Present and potential income of the debtor; and

(3) Whether assets have been concealed or improperly transferred by the debtor.

(b) *Basis for termination of collection action.* Bases on which HCFA may terminate collection action on a claim include the following—

(1) *Inability to collect a substantial amount of the claim.* HCFA may terminate collection action if it determines that it is unable to collect, or to enforce collection, of a significant amount of the claim. In making this determination, HCFA will consider factors such as—

(i) Judicial remedies available;

(ii) The debtor's future financial prospects; and

(iii) Exemptions available to the debtor under State or Federal law.

(2) *Inability to locate debtor.* In cases involving missing debtors, HCFA may terminate collection action if—

(i) There is no security remaining to be liquidated;

(ii) The applicable statute of limitations has run; or

(iii) The prospects of collecting by offset, whether or not an applicable statute of limitations has run, are considered by HCFA to be too remote to justify retention of the claim.

(3) *Cost of collection exceeds recovery.* HCFA may terminate collection action if it determines that the cost of further collection action will exceed the amount recoverable.

(4) *Legal insufficiency.* HCFA may terminate collection action if it determines that the claim is legally without merit.

(5) *Evidence unavailable.* HCFA may terminate collection action if—

(i) Efforts to obtain voluntary payment are unsuccessful; and

(ii) Evidence or witnesses necesary to prove the claim are unavailable.

§ 401.623 Joint and several liability.

(a) *Collection action.* HCFA will liquidate claims as quickly as possible. In cases of joint and several liability among two or more debtors, HCFA will not allocate the burden of claims payment among the debtors. HCFA will proceed with collection action against one debtor even if other liable debtors have not paid their proportionate shares.

(b) *Compromise.* Compromise with one debtor does not release a claim against remaining debtors. Furthermore, HCFA will not consider the amount of a compromise with one debtor to be a binding precedent concerning the amounts due from other debtors who are jointly and severally liable on the claim.

§ 401.625 Effect of HCFA claims collection decisions on appeals.

Any action taken under this subpart regarding the compromise of a claim, or suspension or termination of collection action on a claim, is not an initial determination for purposes of HCFA appeal procedures.

PART 402—[RESERVED]

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Subpart A—[Reserved]

Subpart B—Medicare Supplemental Policies

AUTHORITY: Secs. 1102, 1871, 1874(a), and 1882 of the Social Security Act (42 U.S.C. 1302, 1395hh, 1395kk(a), and 1395ss).

SOURCE: 47 FR 32400, July 26, 1982, unless otherwise noted.

§ 403.200 Basis and scope.

(a) *Provisions of the legislation.* This subpart implements, in part, section 1882 of the Social Security Act. The intent of that section is to enable Medicare beneficiaries to identify Medicare supplemental policies that do not duplicate Medicare, and that provide adequate, fairly priced protection against expenses not covered by Medicare. The legislation establishes certain standards for Medicare supplemental policies and provides two methods for informing Medicare beneficiaries which policies meet those standards:

(1) Through a State approved program, that is, a program that a Supplemental Health Insurance Panel determines to meet certain minimum requirements for the regulation of Medicare supplemental policies; and

(2) In a State without an approved program, through certification by the Secretary of policies voluntarily submitted by insuring organizations for review against the standards.

(b) *Scope of subpart.* This subpart sets forth the standards and procedures HCFA will use to implement the voluntary certification program.

GENERAL PROVISIONS

§ 403.201 State regulation of insurance policies.

(a) The provisions of this subpart do not affect the right of a State to regulate policies marketed in that State.

(b) Approval of a policy under the voluntary certification program, as provided for in § 403.235(b), does not authorize the insuring organization to market a policy that does not conform to applicable State laws and regulations.

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (d) of this section, "Medicare supplemental policy" (policy) means a health insurance policy or other health benefit plan—

(1) That a private entity offers to a Medicare beneficiary; and

(2) That is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) Unless otherwise specified in this subpart, the term "policy" includes both policy form and policy.

(1) "Policy form" means the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) "Policy" means the contract—

(i) Issued under the policy form; and

(ii) Held by the policyholder.

(c) Medicare supplemental policy includes the following—

(1) An individual policy.

(2) A group policy.

(d) Medicare supplemental policy does not include any of the following health insurance policies or health benefit plans—

(1) A policy or plan of one or more employers for employees, former employees, or any combination thereof.

(2) A policy or plan of one or more labor organizations for members, former members, or any combination thereof.

(3) A policy or plan of the trustees of a fund established by one or more

labor organizations, one or more employers, or any combination, for any one or combination of the following—

(i) Employees.

(ii) Former employees.

(iii) Members.

(iv) Former members.

(4) A policy or plan of a profession, trade, or occupational association, if the association—

(i) Is composed of individuals all of whom are actively engaged in the same profession, trade, or occupation;

(ii) Has been maintained in good faith for a purpose other than obtaining insurance; and

(iii) Has been in existence for at least two years before the date of its initial offering of a Medicare supplemental health insurance policy to its members.

(5) For purposes of the voluntary certification program, a policy issued to an employee or to a member of a labor organization as an addition to a franchise plan (a plan that enables members of the same entity to purchase an individual policy marketed to them under group underwriting procedures), if the plan is in existence on July 1, 1982.

§ 403.206 General standards for Medicare supplemental policies.

(a) For purposes of the voluntary certification program described in this subpart, a policy must meet—

(1) The National Association of Insurance Commissioners (NAIC) model standards as defined in § 405.210; and

(2) The loss ratio standards specified in § 403.215.

(b) Except as specified in paragraph (c) of this section, the standards specified in paragraph (a) of this section must be met in a single policy.

(c) In the case of a nonprofit hospital or a medical association where State law prohibits the inclusion of all benefits in a single policy, the standards specified in paragraph (a) of the section must be met in two or more policies issued in conjunction with one another.

§ 403.210 NAIC model standards.

(a) "NAIC model standards" means the National Association of Insurance Commissioners (NAIC) "Model Regulation to Implement the Individual Accident and Insurance Minimum Standards Act" (as amended and adopted by the NAIC on June 6, 1979, as it applies to Medicare supplemental policies). Copies of the NAIC model standards can be purchased from the National Association of Insurance Commissioners at 350 Bishops Way, Brookfield, Wisconsin 53004, and from the NIARS Corporation, 318 Franklin Avenue, Minneapolis, Minnesota 55404.

(b) The policy must comply with the provisions of the NAIC model standards, except as follows—

(1) "Policy", for purposes of this paragraph, means individual and group policy, as specified in § 403.205. The NAIC model standards limit "policy" to individual policy.

(2) The policy must meet the loss ratio standards specified in § 403.215.

[47 FR 32400, July 26, 1982; 49 FR 44472, Nov. 7, 1984]

§ 403.215 Loss ratio standards.

(a) The policy must be expected to return to the policyholders, in the form of aggregate benefits provided under the policy—

(1) At least 75 percent of the aggregate amount of premiums in the case of group policies; and

(2) At least 60 percent of the aggregate amount of premiums in the case of individual policies.

(b) For purposes of loss ratio requirements, policies issued as a result of solicitation of individuals through the mail or by mass media advertising are considered individual policies.

STATE REGULATORY PROGRAMS

§ 403.220 Supplemental Health Insurance Panel.

(a) *Membership.* The Supplemental Health Insurance Panel (Panel) consists of—

(1) The Secretary or a designee, who serves as chairperson, and

(2) Four State Commissioners or Superintendents of Insurance appointed by the President. (The terms Commissioner or Superintendent of Insurance include persons of similar rank.)

(b) *Functions.* (1) The Panel determines whether or not a State regulatory program for Medicare supplemental health insurance policies meets and continues to meet minimum requirements specified in section 1882 of the Social Security Act.

(2) The chairperson of the Panel informs the State Commissioners and Superintendents of Insurance of all determinations made under paragraph (b)(1) of this section.

§ 403.222 State with an approved regulatory program.

(a) A State has an approved regulatory program if the Panel determines that the State has in effect under State law a regulatory program that provides for the application of standards, with respect to each Medicare supplemental policy issued in that State, that are equal to or more stringent than those specified in section 1882 of the Social Security Act.

(b) "Policy issued in that State" means—

(1) A group policy, if the holder of the master policy resides in that State; and

(2) An individual policy, if the policy is—

(i) Issued in that State; or

(ii) Issued for delivery in that State.

(c) A policy issued in a State with an approved regulatory program is considered to meet the NAIC model standards in § 403.210 and loss ratio standards in § 403.215.

VOLUNTARY CERTIFICATION PROGRAM: GENERAL PROVISIONS

§ 403.231 Emblem.

(a) The emblem is a graphic symbol, approved by HHS, that indicates that HCFA has certified a policy as meeting the requirements of the voluntary certification program, specified in § 403.232.

(b) Unless prohibited by the State in which the policy is marketed, the insuring organization may display the emblem on policies certified under the voluntary certification program.

(c) The manner in which the emblem may be displayed and the conditions and restrictions relating to its use will be stated in the letter with which HCFA notifies the insuring organization that a policy has been certified. The insuring organization must comply with these conditions and restrictions.

(d) If a certified policy is issued in a State that later has an approved regulatory program, as provided for in § 403.222, the insuring organization may display the emblem on the policy until the earliest of the following—

(1) When prohibited by State law or regulation.

(2) When the policy no longer meets the requirements for Medicare supplemental policies specified in § 403.206.

(3) The date the insuring organization would be required to submit material to HCFA for annual review in order to retain certification, if the State did not have an approved program (see § 403.239).

§ 403.232 Requirements and procedures for obtaining certification.

(a) To be certified by HCFA, a policy must meet—

(1) The NAIC model standards specified in § 403.210;

(2) The loss ratio standards specified in § 403.215; and

(3) Any State requirements applicable to a policy—

(i) Issued in that State; or

(ii) Marketed in that State.

(b) An insuring organization requesting certification of a policy must submit the following to HCFA for review—

(1) A copy of the policy form (including all the documents that would constitute the contract of insurance that is proposed to be marketed as a certified policy).

(2) A copy of the application form including all attachments.

(3) A copy of the uniform certificate issued under a group policy.

(4) A copy of the outline of coverage, in the form prescribed by the NAIC model standards.

(5) A copy of the Medicare supplement buyers' guide to be provided to all applicants if the buyers' guide is not the HCFA/NAIC buyers' guide.

(6) A statement of when and how the outline of coverage and the buyers' guide will be delivered and copies of applicable receipt forms.

(7) A copy of the notice of replacement and statement as to when and how that notice will be delivered.

(8) A list of States in which the policy is authorized for sale. If the policy was approved under a deemer provision in any State, the conditions involved must be specified.

(9) A copy of the loss ratio calculations, as specified in § 403.250.

(10) Loss ratio supporting data, as specified in § 403.256.

(11) A statement of actuarial opinion, as specified in § 403.258.

(12) A statement that the insuring organization will notify the policyholders in writing, within the period of time specified in § 403.245(c), if the policy is identified as a certified policy at the time of sale and later loses certification.

(13) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy meets the requirements specified in paragraph (a) of this section; and

(ii) The information submitted to HCFA for review is accurate and complete and does not misrepresent any material fact.

§ 403.235 Review and certification of policies.

(a) HCFA will review policies that the insuring organization voluntarily submits, except that HCFA will not review a policy issued in a State with an approved regulatory program under § 403.222.

(b) If the requirements specified in § 403.232 are met, HCFA will—

(1) Certify the policy; and

(2) Authorize the insuring organization to display the emblem on the policy, as provided for in § 403.231.

(c) If HCFA certifies a policy, it will inform all State Commissioners and Superintendents of Insurance of that fact.

§ 403.239 Submittal of material to retain certification.

(a) HCFA certification of a policy that continues to meet the standards will remain in effect, if the insuring organization files the following material with HCFA no later than the date specified in paragraph (b) or (c) of this section—

(1) Any changes in the material, specified in § 403.232(b), that was submitted for previous certification.

(2) The loss ratio supporting data specified in § 403.256(b).

(3) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy continues to meet the requirements specified in § 403.232(a); and

(ii) The information submitted to HCFA for review is accurate and complete and does not misrepresent any material fact.

(b) Except as specified in paragraph (c) of this section, the insuring organization must file the material with HCFA no later than June 30 of each year. The first time the insuring organization must file the material is no later than June 30 of the calendar year that follows the year in which HCFA—

(1) Certifies a new policy; or

(2) Certifies a policy that lost certification as provided in § 403.245.

(c) If the loss ratio calculation period, used to calculate the expected loss ratio for the last actuarial certification submitted to HCFA, ends before the June 30 date of paragraph (b) of this section, the insuring organization must file the material with HCFA no later then the last day of that rate calculation period.

§ 403.245 Loss of certification.

(a) A policy loses certification if—

(1) The insuring organization withdraws the policy from the voluntary certification program; or

(2) HCFA determines that—

(i) The policy fails to meet the requirements specified in § 403.232(a); or

(ii) The insuring organization has failed to meet the requirements for submittal of material specified in § 403.239.

(b) If a policy loses its certification, HCFA will inform all State Commissioners and Superintendents of Insurance of that fact.

(c) If a policy that displays the emblem, or that has been marketed as a certified policy without the emblem, loses certification, the insuring organization must notify each holder of the policy, or of a certificate issued under the policy, of that fact. The notice must be in writing and sent by the earlier of—

(1) The date of the first regular premium notice after the date the policy loses its certification; or

(2) 60 days after the date the policy loses its certification.

§ 403.248 Administrative review of HCFA determinations.

(a) This section provides for administrative review if HCFA determines—

(1) Not to certify a policy; or

(2) That a policy no longer meets the standards for certification.

(b) If HCFA makes a determination specified in paragraph (a) of this section, it will send a notice to the insuring organization containing the following information:

(1) That HCFA has made such a determination.

(2) The reasons for the determination.

(3) That the insuring organization has 30 days from the date of the notice to—

(i) Request, in writing, an administrative review of the HCFA determination; and

(ii) Submit additional information to HCFA for review.

(4) That, if the insuring organization requests an administrative review, HCFA will conduct the review, as provided for in paragraph (c) of this section.

(5) That, in a case involving loss of certification, the HCFA determination will go into effect 30 days from the date of the notice, unless the insuring organization requests an administrative review. If the insuring organization requests an administrative review, the policy retains its certification until HCFA makes a final determination.

(c) If the insuring organization requests an administrative review, HCFA will conduct the review as follows—

(1) A HCFA official, not involved in the initial HCFA determination, will initiate and complete an administrative review within 90 days of the date of the notice provided for in paragraph (b) of this section.

(2) The official will consider—

(i) The original material submitted to HCFA for review, as specified in § 403.232(b) or § 403.239(a); and

(ii) Any additional information, that the insuring organization submits to HCFA.

(3) Within 15 days after the administrative review is completed, HCFA will inform the insuring organization in writing of the final decision, with an explanation of the final decision.

(4) If the final decision is that a policy lose its certification, the loss of certification will go into effect 15 days after the date of HCFA's notice informing the insuring organization of the final decision.

VOLUNTARY CERTIFICATION PROGRAM: LOSS RATIO PROVISIONS

§ 403.250 Loss ratio calculations: General provisions.

(a) *Basic formula.* The expected loss ratio is calculated by determining the ratio of benefits to premiums.

(b) *Calculations.* The insuring organization must calculate loss ratios according to the provisions of §§ 403.251, 403.253, and 403.254.

§ 403.251 Loss ratio date and time frame provisions.

(a) "Initial calculation date" means the first date of the period that the insuring organization uses to calculate the policy's expected loss ratio.

(1) The initial calculation date may be before, the same as, or after the date the insuring organization sends the policy to HCFA for review, except—

(2) The initial calculation date must not be earlier than January 1 of the calendar year in which the policy is sent to HCFA.

(b) "Loss ratio calculation period" means the period beginning with the initial calculation date and ending with the last day of the period for which the insuring organization calculates the policy's scale of premiums.

(c) To calculate "present values", the insuring organization may ignore discounting (an actuarial procedure that provides for the impact of a variety of factors, such as lapse of policies) for loss ratio calculation periods not exceeding 12 months.

§ 403.253 Calculation of benefits.

(a) *General provisions.* (1) Except as provided for in paragraph (a)(2) of this section, calculate the amount of "benefits" by—

(i) Adding the present values on the initial calculation date of—

(A) Expected incurred benefits in the loss ratio calculation period, to—

(B) The total policy reserve at the last day of the loss ratio calculation period: and

(ii) Subtracting the total policy reserve on the initial calculation date from the sum of these values.

(2) To calculate the amount of "benefits" in the case of community or pool rated individual or group policies rerated on an annual basis, calculate the expected incurred benefits in the loss ration calculation period.

(b) *Calculation of total policy reserve*—(1) *Option for calculation.* The insuring organization must calculate "total policy reserve" according to the provisions of paragraph (b)(2) or (3) of this section.

(2) *Total policy reserve: Federal provisions.* (i) "Total policy reserve" means the sum of—

(A) Additional reserve; and

(B) The reserve for future contingent benefits.

(ii) "Additional reserve" means the amount calculated on a net level reserve basis, using appropriate values to account for lapse, mortality, morbidity, and interest, that on the valuation date represents—

(A) The present value of expected incurred benefits over the loss ratio calculation period; less—

(B) The present value of expected net premiums over the loss ratio calculation period.

(iii) "Net premium" means the level portion of the gross premium used in calculating the additional reserve. On the day the policy is issued, the present value of the series of those portions equals the present value of the expected incurred claims over the period that the gross premiums are computed to provide coverage.

(iv) "Reserve for future contingent benefits" means the amounts, not elsewhere included, that provide for the extension of benefits after insurance coverage terminates. These benefits—

(A) Are predicated on a health condition existing on the date coverage ends;

(B) Accrue after the date coverage ends; and

(C) Are payable after the valuation date.

(3) *Total policy reserve: State provisions.* "Total policy reserve" means the total policy reserve calculated according to appropriate State law or regulation.

§ 403.254 Calculation of premiums.

(a) *General provisions.* To calculate the amount of "premiums", calculate the present value on the initial calculation date of expected earned premiums for the loss ratio calculation period.

(b) *Specific provisions.* (1) "Earned premium" for a given period means—

(i) Written premiums for the period; plus—

(ii) The total premium reserve at the beginning of the period; less—

(iii) The total premium reserve at the end of the period.

(2) "Written premiums in a period" means—

(i) Premiums collected in that period; plus—

(ii) Premiums due and uncollected at the end of that period; less—

(iii) Premiums due and uncollected at the beginning of that period.

(3) "Total premium reserve" means the sum of—

(i) The unearned premium reserve;

(ii) The advance premium reserve; and

(iii) The reserve for rate credits.

(4) "Unearned premium reserve" means the portion of gross premiums due that provide for days of insurance coverage after the valuation date.

(5) "Advance premium reserve" means premiums received by the insuring organization that are due after the valuation date.

(6) "Reserve for rate credits" means rate credits on a group policy that—

(i) Accrue by the valuation date of the policy; and

(ii) Are paid or credited after the valuation date.

§ 403.256 Loss ratio supporting data.

(a) For purposes of requesting HCFA certification under § 403.232, the insuring organization must submit the following loss ratio data to HCFA for review—

(1) A statement of why the policy is to be considered, for purposes of the loss ratio standards, an individual or a group policy.

(2) The earliest age at which policyholders can purchase the policy.

(3) The general marketing method and the underwriting criteria used for the selection of applicants to whom coverage is offered.

(4) What policies are to be included under the one policy form, by the dates the policies are issued.

(5) The loss ratio calculation period.

(6) The scale of premiums for the loss ratio calculation period.

(7) The expected level of earned premiums in the loss ratio calculation period.

(8) The expected level of incurred claims in the loss ratio calculation period.

(9) A description of how the following assumptions were used in calculating the loss ratio.

(i) Morbidity.

(ii) Mortality.

(iii) Lapse.

(iv) Assumed increases in the Medicare deductible.

(v) Impact of inflation on reimbursement per service.

(vi) Interest.

(vii) Expected distribution, by age and sex, of persons who will purchase the policy in the coming year.

(viii) Expected impact on morbidity by policy duration of—

(A) The process used to select insureds from among those that apply for a policy; and

(B) Pre-existing condition clauses in the policy.

(b) For purposes of requesting continued HCFA certification under § 403.239(a), the insuring organization must submit the following to HCFA—

(1) A description of all changes in the loss ratio data, specified in paragraph (a) of this section, that occurred since HCFA last reviewed the policy.

(2) The past loss ratio experience for the policy, including the experience of all riders and endorsements issued under the policy. The loss ratio experience data must include earned premiums, incurred claims, and total policy reserves that the insuring organization calculates—

(i) For all years of issue combined; and

(ii) Separately for each calendar year since HCFA first certified the policy.

§ 403.258 Statement of actuarial opinion.

(a) For purposes of certification requests submitted under § 403.232(b) and subsequent review as specified in § 403.239(a), "statement of actuarial opinion" means a signed declaration in which a qualified actuary states that the assumptions used in calculating the expected loss ratio are appropriate and reasonable, taking into account actual policy experience, if any, and reasonable expectations.

(b) "Qualified actuary" means—

(1) A member in good standing of the American Academy of Actuaries; or

(2) A person who has otherwise demonstrated his or her actuarial competence to the satisfaction of the Commissioner or Superintendent of Insurance of the domiciliary State of the insuring organization.

Subpart C—Recognition of State Reimbursement Control Systems

AUTHORITY: Secs. 1102, 1862(a)(14), 1866(a)(1)(F), 1871 and 1886(c) of the Social Security Act (42 U.S.C. 1302, 1395y(a)(14), 1395cc(a)(1)(F), 1395hh and 1395ww(c)).

SOURCE: 51 FR 15492, Apr. 24, 1986, unless otherwise noted.

§ 403.300 Basis and purpose.

(a) *Basis.* This subpart implements section 1886(c) of the Act, which authorizes payment for Medicare inpatient hospital services in accordance with a State's reimbursement control system rather than under the Medicare reimbursement principles as described in HCFA's regulations and instructions.

(b) *Purpose.* Contained in this subpart are—

(1) The basic requirements that a State reimbursement control system must meet in order to be approved by HCFA;

(2) A description of HCFA's review and evaluation procedures; and

(3) The conditions that apply if the system is approved.

§ 403.302 Definitions.

For purposes of this subpart—

"Chief executive officer of a State" means the Governor of the State or the Governor's designee.

"Existing demonstration project" refers to demonstration projects approved by HCFA under the authority of section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 (note)) and in effect on April 20, 1983 (the date of the enactment of Pub. L. 98-21 (Social Security Amendments of 1983)).

"Federal hospital" means a hospital that is administered by, or that is under exclusive contract with, the Department of Defense, the Veterans Administration, or the Indian Health Service.

"State system" or "system" refers to a State reimbursement control system that is approved by HCFA under the authority of section 1886(c) of the Act and that satisfies the requirements described in this subpart.

§ 403.304 Minimum requirements for State systems—discretionary approval.

(a) *Discretionary approval by HCFA.* HCFA may approve Medicare payments under a State system, if HCFA determines that the system meets the requirements in paragraphs (b) and (c) of this section and, if applicable paragraph (d) of this section.

(b) *Requirements for State system.* (1) An application for approval of the system must be submitted to HCFA by the Chief Executive Officer of the State.

(2) The State system must apply to substantially all non-Federal acute care hospitals in the State.

(3) All hospitals covered by the system must have and maintain a utilization and quality control review agreement with a Peer Review Organization, as required under section 1866(a)(1)(F) of the Act and § 466.78(a) of this chapter.

(4) Federal hospitals must be excluded from the State system.

(5) Nonacute care or specialty hospital (such as rehabilitation, psychiatric, or children's hospitals) may, at the option of the State, be excluded from the State system.

(6) The State system must apply to at least 75 percent of all revenues or expenses—

(i) For inpatient hospital services in the State; and

(ii) For inpatient hospital services under the State's Medicaid plan.

(7) Under the system, HMOs and competitive medical plans (CMPs), as defined by section 1876(b) of the Act and Part 417 of this chapter, must be allowed to negotiate payment rates with hospitals.

(8) The system must limit hospital charges for Medicare beneficiaries to deductibles, coinsurance or non-covered services.

(9) Unless a waiver is granted by HCFA under § 489.23 of this chapter, the system must prohibit payment, as required under section 1862(a)(14) of the Act and § 405.310(m) of this chapter, for nonphysician services provided to hospital inpatients under Part B of Medicare.

(10) The system must require hospitals to submit Medicare cost reports or approved reports in lieu of Medicare cost reports as required.

(11) The system must require—

(i) Preparation, collection, or retention by the State of reports (such as financial, administrative, or statistical reports) that may be necessary, as determined by HCFA, to review and monitor the State's assurances; and

(ii) Submission of the reports to HCFA upon request.

(12) The system must provide hospitals an opportunity to appeal errors that they believe have been made in the determination of their payment rates. The system, if it is prospective may not permit providers to file administrative appeals that would result

in a retroactive revision of prospectively determined payment rates.

(c) *Satisfactory assurances.* The State must provide to HCFA satisfactory assurance as to the following:

(1) The system provides for equitable treatment of hospital patients and hospital employees.

(2) The system provides for equitable treatment of all entities that pay hospitals for inpatient hospital services, including Federal and State programs. Under the requirement, the following conditions must be met:

(i) Both the Medicare and Medicaid programs must participate under the system.

(ii) The State must assure equitable and uniform treatment under the system of third-party payors of inpatient hospital services in terms of opportunity. Equitable opportunity must include, but need not be limited to, participation in the system and availability of discounts. Criteria under which discounts are made available must be equitably and uniformly applied to all payors, except for discounts negotiated by HMOs and CMPs. Discounts available to HMOs and CMPs as result of their statutory right to negotiate payment rates independently of a State system, as described in paragraph (b)(7) of this section, need not be available to other payors.

(iii) The State must assure that all third-party payors that participate under the system share in the system's risks and benefits.

(3) The amount of Medicare payments made under the system over 36-month periods may not exceed the amount of Medicare payment that would otherwise have been made under the Medicare principles of reimbursement for Medicare items and services had the State system not been in effect. States must submit the assurance and supporting data as required by § 403.320 to document that the payment limit is not exceeded. States that have an existing Medicare demonstration project in effect on April 20, 1983, and that have requested approval of a State system under section 1886(c)(4) of the Act, may elect to have the effectiveness of the State system under this paragraph judged on the basis of the State system's rate of increase or inflation in Medicare inpatient hospital payments as compared to the national rate of increase or inflation for such payments during the three cost reporting periods of the hospitals in the State beginning on or after October 1, 1983.

(d) *Additional cost-effectiveness assurance.* If the assurances and supporting data required under paragraph (c)(3) of this section are insufficient to provide assurance satisfactory to HCFA regarding the cost-effectiveness of a State system, the State may additionally submit one of the following assurances in order to meet the cost-effectiveness test:

(1) *State responsibility for excess payments.* The State must agree that each month Medicare intermediaries will disburse to the State's hospital Federal funds that in the aggregate equal no more than would have been disbursed in the absence of the State system. Any additional funds necessary to pay hospitals for Medicare services required by the State system will be paid to the intermediaries by the State. These additional amounts will be refunded to the State by the intermediaries to the extent that, in subsequent months, the State system requires a smaller aggregate payment for Medicare services than would have been paid in the absence of the State system.

(2) *Limitations on payments.* (i) The State must agree that if its projections exceed what Medicare would pay in any particular period, the State and HCFA will establish and agreed upon payment schedule that will limit payments under the State system based on a predetermined percentage relationship between projected State payments and what payments would have been under Medicare.

(ii) If deviation from the predetermined relationship described in paragraph (d)(2)(i) of this section occurs, the State must further agree that—

(A) Medicare payments would be capped automatically at payment levels based on the rates used for the Medicare prospective payment system and the State would be required to pay the difference to individual hospitals in its system; or

(B) The State may provide by legislation or legally binding regulations that any reduced payments to hospitals under the system that result from this cost-effectiveness assurance will constitute full and final payment for hospital services furnished to Medicare beneficiaries for the period covered by these reduced payments.

§ 403.306 Additional requirements for State systems—mandatory approval.

(a) *General policy*—(1) *Mandatory approval.* HFCA will approve an application for Medicare reimbursement under a State system if the system meets all of the requirements of § 403.304 and of paragraph (b) of this section.

(2) *Exception.* HCFA may approve an application if the State system meets all of the requirements of § 403.304 but only some of the requirements of paragraph (b) of this section.

(b) *Additional requirements*—(1) *Operation of system.* The system must—

(i) Be operated directly by the State or by entity designated under State law;

(ii) Provide for payments to hospitals using a methodology under which—

(A) Prospectively determined payment rates are established; and

(B) Exceptions, adjustments, and methods for changes in methodology are set forth;

(iii) Provide that a change by the State in the system that has the effect of materially changing payments to hospitals can take effect only upon 60 days notice to HCFA and to the hospitals likely to be materially affected by the change and upon HCFA's approval of the change.

(2) *Satisfactory assurances*—(i) *Admissions practice.* The State must assure that the operation of the system will not result in any change in hospital admission practices that result in—

(A) A significant reduction in the proportion of patients receiving hospital services covered under the system who have no third-party coverage and who are unable to pay for hospital services;

(B) A significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is less, or is likely to be less, than the anticipated charges for or cost of the services;

(C) A refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital; or

(D) A refusal to provide emergency services to any person who is in need of emergency services, if the hospital provides the services.

(ii) *Consultation with local government officials.* The State must provide documentation that it has consulted with local government officials concerning the impact of the system on publicly owned or operated hospitals.

§ 403.308 State systems under demonstration projects—mandatory approval.

HCFA will approve an application from a State for a State system if—

(a) The system was in effect prior to April 20, 1983 under an existing demonstration project; and

(b) The minimum requirements and assurances for approval of a State system are met under § 403.304 (b)(1)-(10) and § 403.304(c), and, if appropriate § 403.304(d).

§ 403.310 Reduction in payments.

(a) *General rule.* If HCFA determines that the satisfactory assurances required of a State under § 403.304(c) and, if applicable, § 403.304(d) have not been met, or will not be met, with respect to any 36-month period, HCFA will reduce Medicare payments to individual hospitals being reimbursed under the State's system or, if applicable, under the Medicare payment system, in an amount equal to the amount by which the Medicare payments under the system exceed the amount of Medicare payments to such hospitals that otherwise would have been made not using the State system. The amount of the recoupment will include, when appropriate, interest charges computed in accordance with § 405.376 of this chapter.

(b) *Recoupment procedures.* The amount of the overpayment will be recouped on a proportionate basis from each of those hospitals that received payments under the State system that exceeded the payments they would have received under the Medicare payment system. Each hospital's share of the aggregate excess payment will be determined on the basis of a comparison of the hospital's proportionate share of the aggregate payment received under the State system that is in excess of what the aggregate payment would have been under the Medicare payment system. Recoupments may be accomplished by a hospital's direct payment to the Medicare program or by offsets to future payments made to the hospital.

(c) *Alternative recoupment procedures.* As an alternative to the recoupment procedures described in paragraph (b) of this section and subject to HCFA's acceptance, the State may provide, by legislation or legally binding regulations, procedures for the recoupment of the amount of payments that exceed the amount of payments that otherwise would have been paid by Medicare if the State system had not been in effect.

(d) *Rule for existing Medicare demonstration projects.* In cases of existing Medicare demonstration projects where the expenditure test is to be applied by a rate of increase factor, the amount of the excess payment will be determined, for the three hospital cost reporting periods beginning before October 1, 1986, by a comparison of the State system's rate of increase to the national rate of increase. Recoupment of excessive payments will be assessed and recouped as described in this section.

§ 403.312 Submittal of application.

The Chief Executive Officer of the State is responsible for—

(a) Submittal of the application to HCFA for approval; and

(b) Supplying the assurances and necessary documentation as required under §§ 403.304 through 403.308.

§ 403.314 Evaluation of State systems.

HCFA will evaluate all State applications for approval of State systems and notify the State of its determination within 60 days.

§ 403.316 Reconsideration of certain denied applications.

(a) *Request for reconsideration.* If HCFA denies an application for a State system, the State may request that HCFA reconsider the denial if the State believes that its system meets all of the requirements for mandatory approval under §§ 403.304 and 403.306 or, in the case of a State with a system operating under an existing demonstration project, the applicable requirements of §§ 403.304 and 403.308.

(b) *Time limit.* (1) The State must submit its request for reconsideration within 60 days after the date of HCFA's notice that the application was denied.

(2) HCFA will notify the State of the results of its reconsideration within 60 days after it receives the request for reconsideration.

§ 403.318 Approval of State systems.

(a) *Approval agreement.* If HCFA approves a State system, a written agreement will be executed between HCFA and the Chief Executive Officer of the State. The agreement must incorporate any terms of the State's application for approval of the system as agreed to by the parties and, as a minimum, must contain provisions that require the following:

(1) The system is operated directly by the State or an entity designated by State law.

(2) For purposes of the Medicare program, the State's system applies only to Medicare payments for inpatient, and if applicable, outpatient hospital services.

(3) The system conforms to applicable Medicare law and regulations other than those relating to the amount of reimbursement for inpatient hospital services, or for inpatient and outpatient services, whichever the State system covers. Applicable regulations include, for example, those describing Medicare benefits and entitlement requirements for program beneficiaries, as explained in Parts 406 and 409 of this chapter; the requirements at Part 405, Subpart J of this chapter specifying conditions of participation for hospitals; the requirements at Part

405, Subparts A, G, and S of this chapter on Medicare program administration; and all applicable fraud and abuse regulations contained in titles 42 and 45 of the CFR.

(4) The State must obtain HCFA's approval of the State's reporting forms and of provider cost reporting forms or other forms that have not been approved by HCFA but that are necessary for the collection of required information.

(b) *Effective date.* An approved State system may not be effective earlier than the date of the approval agreement, which may not be retroactive.

§ 403.320 HCFA review and monitoring of State systems.

(a) *General rule.* The State must submit an assurance and detailed and quantitative studies of provider cost and financial data and projections to support the effectiveness of its system, as required by paragraphs (b) and (c) of this section.

(b) *Required information.* (1) Under § 403.304(c)(3) an assurance is required that the system will not result in greater payments over a 36-month period than would have otherwise been made under Medicare not using such system. If a State that has an existing demonstration project in effect on April 20, 1983 elects under § 403.304(c)(3) to have the effectiveness of its system judged on the basis of a rate of increase factor, the State must submit an assurance that its rate of increase or inflation in inpatient hospital payments does not exceed, for that portion of the 36-month period that is subject to this test, the national rate of increase or inflation in Medicare inpatient hospital payments. The election of the rate of increase test applies only to the three cost reporting periods beginning on or after October 1, 1983. At the end of these cost reporting periods, the State must assure, beginning with the first month after the expiration of the third cost reporting period beginning after October 1, 1983, that payments under its system will not exceed over the remainder of the 36-month period what Medicare payments would have been.

(2) Estimates and data are required to support the State's assurance, required under § 403.304(c)(3), that expenditures under the State system will not exceed what Medicare would have paid over a 36-month period. The estimates and projections of what Medicare would have otherwise paid must take into account all the Medicare reimbursement principles in effect at the time and, for any period in which payments either exceed or are less than Medicare levels, the values of interest the Medicare Trust Fund earned, or would have earned, on these amounts. Upon application for approval, the State must submit projections for each hospital for the first 12-month period covered by the assurance, in both the aggregate and on a per discharge basis, of Medicare inpatient expenditures under Medicare principles of reimbursement and parallel projections of Medicare inpatient expenditures under the State's system and the resulting cost or savings to Medicare. The State must also submit separate statewide projections for each year of the 36-month period, in both the aggregate and on a weighted average discharge basis, of inpatient expenditures under the State system and under the Medicare principles of reimbursement.

(3) The projection submitted under paragraph (b)(2) of this section must include a detailed description of the methodology and assumptions used to derive the expenditure amounts under both systems. In instances where the assumptions are different under the projections cited in paragraph (b)(2) of this section, the State must provide a detailed explanation of the reasons for the differences. At a minimum, the following separate data and assumptions are to be included in the projections for the Medicare principles and for the State's system.

(i) The State system base year and the Medicare allowable and reimbursable cost of each hospital that the State used to develop the projections, including the amount of estimated pass through costs.

(ii) The categories of costs that are included in the State system and are reimbursed differently under the State system than under the Medicare system.

(iii) The number of Medicare and total base year discharges and admissions for each hospital.

(iv) The rate of change factor (and the method of application of this factor) used to project the base year costs over the 36-month period to which the assurance would apply.

(v) Any allowance for anticipated growth in the amount of services from the base year (if applicable, the allowance must be presented in separate estimates for population increases or for increases in rates of admissions or both).

(vi) Any adjustment in which the State is permitted by HCFA to take into account previous reductions in the Medicare payment amounts that were the result of the effectiveness of the State's system even though Medicare was not a part of that system.

(vii) Appropriate recognition and projection of the time value of trust fund expenditures for the period the State system expenditures were either less than or exceeded the Medicare system payments.

(viii) States applying under a rate of increase effectiveness test under § 403.304(c)(3) must also submit data projecting the parallel rates of increase during the requisite period.

(4) The projections must include both the aggregate payments and the payments per discharge for the individual hospitals and for the State as a whole.

(5) On a case-by-case basis. HCFA may require additional data and documentation as needed to complete its review and monitoring.

(6) For existing Medicare demonstration projects in effect on April 20, 1983, the assurance and data as required by paragraphs (a) and (b) of this section, if appropriate, may be based on aggregate payments or payments per inpatient admission or discharge. HCFA will judge the effectiveness of these systems on the basis of the rate of increase or inflation in Medicare inpatient hospital payments compared to the national rate of increase or inflation for such payments during the State's hospitals' three cost reporting periods beginning on or after October 1, 1983. The data submitted by the State for the period subject to the rate of increase test must include the rate of increase projection for that particular period of time. For the subsequent period of time, the State must assure that payments under its system will not exceed what Medicare payments would have been, as described in § 403.304(c)(3).

(7) If the amount of Medicare payments under the State system exceeds what would have been paid under the Medicare reimbursement principles in any given year, the State must also submit quantitative evidence that the system will result in expenditures that do not exceed what Medicare expenditures would have been over the 36 month period beginning with the first month that the State system is operating. For a State that has an existing demonstration project in effect on April 20, 1983, and that elects under § 403.304(c)(3) to have a rate of increase test apply, if the State's rate of increase or inflation exceeds the national rate of increase or inflation in a given year, the State must submit quantitative evidence that, over 36 months, its payments will not exceed the national rate of increase or inflation. Furthermore, if payments under the State's system must be compared to actual Medicare expenditures, at the end of the third cost reporting period, as described in paragraph (b)(1) of this section, and payments under the State's system exceed what Medicare would have paid in a given year, the State must submit quantitative evidence that, over 36 months, payments under its system will not exceed what Medicare would have paid.

(c) *Review of assurances regarding expenditures.* HCFA will review the State's assurances and data submitted under this section, as a prerequisite to the approval of the State's system. HCFA will compare the State's projections of payment amounts to HCFA data in order to determine if the State's assurance is reasonable and fully supportable. If the HCFA data indicate that the State's system would result in payment amounts that would be more then that which would have been paid under the Medicare principles, the State's assurances would not be acceptable. For States applying in accordance with § 403.308, if HCFA data indicate that the State's system would result in a rate of increase or inflation that would be more than the national rate of increase or inflation, the State's assurances would not be acceptable.

(d) *Medicaid upper limit.* In accordance with § 447.253 of this chapter, the State system may not result in aggregate payments for Medicaid inpatient hospital services that would exceed the amount that would have otherwise have been paid under the Medicare principles as applied through the State system.

(e) *Monitoring of Medicare expenditures.* HCFA will monitor on a quarterly basis expenditures under the State's system as compared to what Medicare expenditures would have been if the system had not been in effect. If HCFA determines at any time that the payments made under the State's system exceed the States' projections, as established by the satisfactory assurances required under § 403.304(c) and, if appropriate, the predetermined percentage relationship of the payments as required under § 403.304(d). HCFA will—

(1) Conclude that payments under the State system over a 36 month period will exceed what Medicare would have paid:

(2) Terminate the waiver; and

(3) Recoup overpayments to the affected hospitals in accordance with the procedures described in § 403.310.

§ 403.321 State systems for hospital outpatient services.

HCFA may approve a State's application for approval of an outpatient system if the following conditions are met:

(a) The State's inpatient system is approved.

(b) The State's outpatient application meets the requirements and assurances for an inpatient system described in § 403.304 (b) and (c), and § 403.306 (b)(1) and (b)(2)(ii).

(c) The State submits a separate application that provides separate assurances and estimates and data in further support of its assurance submitted under paragraph (b)(1) of § 403.320, as follows:

(1) Upon application for approval, the State must submit estimates and data that include, but are not limited to, projections for the first 12-month period covered by the assurance for each hospital, in both the aggregate and on an average cost per service and payment basis, of Medicare outpatient expenditures under Medicare principles of reimbursement; parallel projections of Medicare outpatient expenditures under the State system; and the resulting cost or savings to Medicare independent of the State system for hospital inpatient services.

(2) The State must submit separate statewide projections for each year of the 36-month period of the aggregate outpatient expenditures for each system. The projections submitted under this paragraph must—

(i) Comply with the requirements of paragraphs (b) (3) and (5) of § 403.320 regarding a detailed description of the methodology used to derive the expenditure amounts:

(ii) Include the data and assumptions set forth in paragraphs (b)(3) (i), (ii), (iii), (iv), and (v) of § 403.320; and

(iii) Include any assumption the State has adopted for establishing the number of Medicare and total base year outpatient services for each hospital.

(3) The State must provide a detailed explanation of the reasons for any difference between the data or assumptions used for the separate projections.

§ 403.322 Termination of agreements for Medicare recognition of State systems.

(a) *Termination of agreements.* (1) HCFA may terminate any approved agreement if it finds, after the procedures described in this paragraph are followed that the State system does not satisfactorily meet the requirements of section 1886(c) of the Act or the regulations in this subpart. A termination must be effective on the last day of a calendar quarter.

(2) HCFA will give the State reasonable notice of the proposed termination of an agreement and of the reasons for the termination at least 90 days before the effective date of the termination.

(3) HCFA will give the State the opportunity to present evidence to refute the finding.

(4) HCFA will issue a final notice of termination upon a final review and determination on the State's evidence.

(b) *Termination by State.* A State may voluntarily terminate a State system by giving HCFA notice of its intent to terminate. A termination must be effective on the last day of a calendar quarter. The State must notify HCFA of its intent to terminate at least 90 days before the effective date of the termination.

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PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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EDITORIAL NOTES: 1. Part 405 of Title 20 was transferred into Title 42 at 42 FR 52826, September 30, 1977. As a result of the transfer, all section numbers in this part are remaining the same and now appear as 42 CFR Part 405.

2. Nomenclature changes affecting this Part 405 appear at 38 FR 3597, Feb. 8, 1973; 38 FR 26718, Sept. 25, 1973; 41 FR 51588, Nov. 23, 1976; 42 FR 65113, Dec. 29, 1977; 48 FR 22924, May 23, 1983.

Subpart A—[Reserved]

Subpart B—Supplementary Medical Insurance Enrollment and Entitlement

AUTHORITY: Secs. 1102, 1836-1838, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395o-1395q, and 1395hh) unless otherwise noted.

SOURCE: 36 FR 16647, Aug. 25, 1971, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

GENERAL PROVISIONS

§ 405.201 Scope.

This subpart sets forth the conditions and procedures for enrollment in the Supplementary Medical Insurance (SMI) program.

[51 FR 41336, Nov. 14, 1986]

§ 405.202 Enrollment; general.

To become entitled to supplementary medical insurance benefits, an individual must meet the eligibility requirements for enrollment (see § 405.205) and must enroll (see § 405.210) or be enrolled pursuant to an agreement with a State (see § 405.217) in the supplementary medical insurance plan.

ENROLLMENT AND COVERAGE

§ 405.205 Eligibility requirements for enrollment.

An individual is eligible for enrollment in the supplementary medical insurance plan (unless excluded under § 405.206) if he either:

(a) Is entitled to hospital insurance under Part A of title XVIII of the Act (see §§ 408.10 through 408.22 of this chapter); or

(b) Has attained age 65 and is a resident of the United States *and* is either a citizen, or an alien lawfully admitted for permanent residence who has resided in the United States continuously during the 5 years immediately preceding the month in which he applies for enrollment under the regulations in this part.

[40 FR 18165, Apr. 25, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 4429, Feb. 2, 1978]

§ 405.206 Persons ineligible to enroll.

Notwithstanding the provisions specified in § 405.205, an individual is not eligible for enrollment in the supplementary medical insurance plan if he has been convicted of any offense under chapter 37 (relating to espionage and censorship), chapter 105 (relating to sabotage), or chapter 115 (relating to treason, sedition, and subversive activities) of title 18 of the United States Code, or under sections 4, 112, or 113 of the Internal Security Act of 1950, as amended (relating to conspiracies to establish dictatorships and conspiracies to commit espionage or sabotage).

§ 405.207 Forms used to apply for enrollment under Medicare Part B.

The following forms, available free of charge by mail from HCFA, or at any Social Security branch or district office, are used to apply for enrollment under the supplementary medical insurance program.

HCFA-4040—Application for Enrollment in the Supplementary Medical Insurance Program. (This form is used for enrollment by individuals who are not eligible for monthly benefits or for hospital insurance.)

HCFA-40-B—Application for Medical Insurance. (For general use by the SSA District Office in requesting medical insurance protection during the general enrollment period or during the initial enrollment period if the enrollee is not subject to automatic enrollment is SMI.)

HCFA-40-D—Application for Enrollment in the Suplementary Medical Insurance Program. (This form is mailed to individuals who do not have current supplementary medical insurance because of prior refusals, voluntary withdrawal, or premium default from prior coverage. It is used during the annual general enrollment period.)

HCFA-40-F—Application for Medical Insurance. (For use by beneficiaries residing outside the United States.)

HCFA-18-F-5—Application for Hospital Insurance Entitlement. (For use by individuals who are not eligible for retirement benefits under Title II of the Social Security Act or under the Railroad Retirement Act. This form may also be used for enrollment in the supplementary medical insurance program.)

As an alternative, the individual may request enrollment by answering the Part B enrollment questions on an application for monthly Social Security benefits, or by signing a simple statement of request, if he or she is eligible to enroll at that time.

[53 FR 6633, Mar. 2, 1988]

§ 405.210 Individual enrollment; enrollment procedures.

(a) *What constitutes enrollment.* To enroll in the supplementary medical insurance program, an eligible individual (see § 405.205) must:

(1) File with the Social Security Administration or the Health Care Financing Administration, during a period of enrollment (see §§ 405.211 through 405.214) open to such individual, a written request for enrollment, signed by him or on his behalf; or

(2) Be deemed to have enrolled in accordance with the provisions of paragraph (b) of this section.

(b) *Automatic enrollment.* Any individual who is eligible to enroll in the supplementary medical insurance plan by reason of entitlement to hospital insurance and who is residing in the United States, exclusive of Puerto Rico, shall, unless he timely declines such insurance in accordance with paragraph (c) of this section, be deemed to have enrolled in the supplementary medical insurance plan as follows:

(1) He will be deemed to have enrolled for supplementary medical insurance in the third month of his initial enrollment period if:

(i) He was entitled to monthly cash benefits under section 202 of the Act on the first day of his initial enrollment period;

(ii) He becomes entitled to monthly benefits under section 202, by filing application and meeting all other requirements during the first 3 months of that period;

(iii) He is eligible for monthly social security cash benefits under section 202 of the Act and has filed an application for hospital insurance during the first 3 months of that period (effective as specified in § 406.10 of this chapter); or

(iv) He is entitled to hospital insurance based on entitlement to social security disability benefits under § 406.12 of this chapter, or end-stage renal disease under § 406.13 of this chapter).

(c) *Opportunity to decline deemed enrollment.* Every person who has not actually requested enrollment but is deemed to have enrolled under paragraph (b) of this section will be given opportunity to decline such deemed enrollment as follows: he will be mailed notice of his deemed enrollment and advised by such notice that he may decline supplementary medical insurance and will be deemed not to have enrolled if he files with the Social Security Administration or the Health Care Financing Administration, before his coverage begins or, if later, within a specified period (not less than 2 calendar months) after the month in which such notice is mailed to him, his signed statement that he does not wish such insurance.

(Secs. 226A, 1102, and 1837 of the Social Security Act (42 U.S.C. 426-1, 1302, and 1395(p)))

[40 FR 18166, Apr. 25, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 12535, Mar. 25, 1983; 51 FR 41351, Nov. 14, 1986]

§ 405.211 Individual enrollment; enrollment periods; general.

An individual may enroll in the supplementary medical insurance plan only during an "enrollment period." There are two kinds of enrollment periods—the "initial enrollment period" (see § 405.212), which is based on the time when the individual first meets the eligibility requirements for enrollment, and the "general enrollment period" (see § 405.213) during which an individual who failed to enroll during his initial enrollment period or whose enrollment has been terminated may, with certain limitations, first enroll, or reenroll (see § 405.224 relating to good cause for failure to enroll).

§ 405.212 Individual enrollment; initial enrollment period.

(a) *General.* An individual's first opportunity to enroll in the supplementary medical insurance plan is called his "initial enrollment period." The beginning and ending dates of an individual's initial enrollment period are determined by the month in which he first meets the eligibility requirements for enrollment (see § 405.205).

(b) [Reserved]

(c) *Individual first eligible after February 1966.* If an individual first meets the eligibility requirements in § 405.205 after February 1966, his initial enrollment period begins on the first day of the third month before the month in which he first meets such requirements and ends with the close of the last day of the third month following the month in which he first satisfies such requirements.

(d) *First eligibility for enrollment; individual eligible solely because of entitlement to hospital insurance benefits.* For purposes of determining the initial enrollment period of an individual who is eligible for enrollment solely because he is entitled to hospital insurance benefits (see § 405.205(a)), the individual is considered as first meeting the eligibility requirements for enrollment on the first day on which he would be entitled to hospital insurance benefits upon filing application therefor whether or not he so filed.

(e) *Deemed initial enrollment period.* Notwithstanding the provision of paragraphs (a), (b), (c), and (d) of this section, where the Social Security Administration finds that an eligible individual under Subpart B of Part 408 of this chapter failed to enroll during his initial enrollment period (based on a determination by the Administration of the month in which such individual attained age 65), because such individual (relying on erroneous documentary evidence) was mistaken as to his correct date of birth, the Administration shall, on the basis of a written request for enrollment filed on or after February 1, 1968, establish for such individual a deemed initial enrollment period based on his attaining age 65 at the time indicated by such documentary evidence with a coverage period determined under § 405.221 (c) or (d) as though he had attained age 65 at that time. Such deemed initial enrollment period will also be used in determining the amount of the individual's premiums under Subpart B of Part 408 of this chapter and his right to enroll in a general enrollment period, where the use of such deemed initial enrollment period is material and advantageous to the individual.

[36 FR 16647, Aug. 25, 1971 Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 4429, Feb. 2, 1978; 52 FR 48123, Dec. 18, 1987]

§ 405.213 Individual enrollment; general enrollment periods.

(a) There shall be a general enrollment period beginning on October 1, 1967, and ending on March 31, 1968, followed by subsequent general enrollment periods which shall begin on January 1 and end on March 31 of each calendar year beginning with the calendar year 1969. An individual who fails to enroll in the supplementary medical insurance plan during his initial enrollment period, or whose enrollment has been terminated, may enroll thereafter only during a general enrollment period.

[36 FR 16647, Aug. 25, 1971, as amended at 40 FR 18166, Apr. 25, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 4429, Feb. 2, 1978]

§ 405.214 Individual enrollment; limitation on enrollment and reenrollment.

(a) [Reserved]

(b) *Delayed enrollment or reenrollment after October 29, 1972.* Effective

October 30, 1972, an individual who did not enroll during his initial enrollment period or whose enrollment has terminated may enroll or reenroll, thereafter, subject to the provisions of paragraph (c) of this section only during a general enrollment period (whether or not such general enrollment period begins within 3 years after the last day of his initial enrollment period or of his prior period of coverage).

(c) *Limitation on number of enrollments.* No individual may enroll in the supplementary medical insurance plan more than twice. For purposes of this paragraph, the first reenrollment by an individual following the termination of any prior enrollment for which he was deemed under the provisions of § 405.223(d) to have enrolled, shall, without regard to any previous enrollment or termination of enrollment, be deemed a second enrollment by the individual.

(d) *Separate continuous period of eligibility.* Each period throughout which an individual has been entitled to hospital insurance and which terminated before the month he attained age 65 shall be considered to be a separate continuous period of eligibility, and shall be deemed not to have existed for purposes of determining his enrollment rights under this section during a subsequent separate continuous period of eligibility.

[36 FR 16647, Aug. 25, 1971, as amended at 39 FR 2757, Jan. 24, 1974; 40 FR 18166, Apr. 25, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 4429, Feb. 2, 1978]

§ 405.215 Individual enrollment; enrollment periods ending on a nonworkday.

Notwithstanding the provisions of §§ 405.212 and 405.213, where the last day of an individual's initial enrollment period (§ 405.212) or the last day of a general enrollment period (§ 405.213) falls on a nonworkday (Saturday, Sunday, legal holiday, or a day all or part of which is declared to be a nonworkday for Federal employees by statute or Executive order), a written request for enrollment (see § 405.210) received by the Social Security Administration or the Health Care Financing Administration on the first workday thereafter will be considered to have been received on the last preceding workday.

§ 405.216 Special enrollment periods related to coverage under an employer group health plan.

(a) *General rules.* Special enrollment periods (SEPs) are 7-month periods available to individuals who meet the general requirements of this paragraph (a), and the special conditions set forth in paragraph (b) or (c) of this section, as appropriate.

(1) They are eligible to enroll in SMI on the basis of age or disability, but not on the basis of end-stage renal disease.

(2) When first eligible to enroll in SMI (4th month of their initial enrollment period),

(i) They were covered under an employer group health plan; or

(ii) They enrolled in SMI during their initial enrollment period.

(3) Except as provided in paragraph (a)(4) of this section, they maintained coverage under either an employer group health plan or SMI for all months after the initial enrollment period.

(4) *Exception:* If an individual failed to enroll during any SEP because employer group health plan coverage was restored before the end of that SEP, that failure to enroll in SMI is not considered a break in coverage that would preclude another SEP now or in the future.

(b) *Specific rules: Individual age 65 or over.* Individuals entitled on the basis of age must meet the following conditions:

(1) They have been covered, on the basis of current employment, under an employer group health plan as defined in section 162(i)(3) of the Internal Revenue Code of 1954; and

(2) They are no longer covered under such a plan on the basis of current employment.

(c) *Specific rules: Disabled individual.* Individuals entitled on the basis of disability (but not on the basis of end-stage renal disease), must meet the following conditions:

(1) They have been covered under a large employer group health plan that

meets the definition in section 5000(b) of the Internal Revenue Code of 1954;

(2) They had this coverage as an employee, employer, individual associated with the employer in a business relationship, or as a family member of one of the foregoing; and

(3) They no longer have the coverage described in this paragraph (c).

(d) *Beginning of special enrollment period: Individual age 65 or over.* For an aged individual—

(1) Before May 1986, the SEP began with whichever of the following resulted in earlier SMI entitlement:

(i) The first day of the third month before the month in which the individual attained age 70, if employer group health plan coverage continued to age 70.

(ii) The first day of the first month in which the individual was no longer enrolled in an employer plan on the basis of current employment.

(2) In and after May 1986, the SEP begins on the first day of the first month in which the individual is no longer enrolled in an employer plan on the basis of current employment.

(e) *Beginning of special enrollment period: Disabled individual.* For a disabled individual under age 65, the SEP begins with the first day of the first month after December 1986 in which the individual is no longer covered under an employer plan as described in paragraph (c) of this section. Because the provisions applicable to disabled individuals expire on December 31, 1991, the last SEP available under those provisions will begin with January 1992.

(f) *Beginning of special enrollment period: Partial coverage month.* When employer plan coverage ends before the end of a month, the following rules apply—

(1) If the individual enrolls in SMI before the end of the partial coverage month, the SEP begins with that month.

(2) If the individual does not enroll in SMI before the end of the partial coverage month, the SEP begins with the following month.

(g) *Beginning of Entitlement*—(1) *Enrollment or reenrollment before May 1986.* (i) If an individual enrolled during the 3 months before attainment of age 70, entitlement began with the month of attainment of age 70; and

(ii) If an individual enrolled during the month of attainment of age 70, or during any of the 3 following months, entitlement began with the month after the month of enrollment.

(2) *Enrollment or reenrollment in and after May 1986.* (i) If an individual enrolls during the first month of nonenrollment in an employer group health plan, which is the first month of the SEP, entitlement begins with the first day of that month.

(ii) If an individual enrolls during the last 6 months of the SEP, entitlement begins with the month after the month of enrollment.

[52 FR 48114, Dec. 18, 1987]

§ 405.217 Enrollment pursuant to a State agreement.

(a) Subject to the provisions of paragraph (c) of this section, the Secretary shall enter into an agreement with any State which so requests before 1970, pursuant to which the State will enroll in the supplementary medical insurance plan (without regard to any prior enrollment or termination of enrollment) all eligible individuals in either of the coverage groups described in paragraph (b) of this section (as specified in the agreement), and pay the premiums due for each such individual so enrolled for all months in his coverage period, beginning as provided in § 405.222 and ending as provided in § 405.223(c).

(b) Subject to paragraphs (g) and (h) of this section, an agreement entered into with any State pursuant to paragraph (a) of this section shall be applicable to either of the following coverage groups:

(1) Individuals receiving money payments under the plan of such State approved under title I or title XVI of the Act; or

(2) All individuals receiving money payments under any of the plans of such State approved under titles I, X, XIV, XVI, and Part A of title IV of the Act.

(c) Notwithstanding the provisions of paragraph (b) of this section:

(1) An individual may not, subject to paragraphs (c)(2) and (g)(5) of this section, be a member of the coverage group specified in an agreement entered into under paragraph (a) of this section for any month in which he is entitled to monthly benefits under title II of the Social Security Act or entitled to receive an annuity or pension under the Railroad Retirement Act of 1937 (without regard to the retroactivity of such entitlement) unless the State requests before 1970, and the agreement is modified to provide, that such individuals shall be members of such coverage group.

(2) The coverage group specified in an agreement entered into under paragraph (a) of this section shall, at the request of the State made before 1970, be modified to provide for the inclusion of all eligible individuals (including individuals entitled to monthly benefits under title II of the Act or entitled to receive an annuity or pension under the Railroad Retirement Act of 1937) whom the State determines to be eligible to receive medical assistance under the plan of such State approved under title XIX of the Social Security Act.

(3) Any individual whom the State has determined to be an eligible member and included in its agreement with the Secretary pursuant to section 1843 of the Act, shall be deemed to be an eligible member of such coverage group for the purpose of enrollment in the supplementary medical insurance plan under such State's agreement with the Secretary. See § 405.223(c) for the termination date of such individual's supplementary medical insurance coverage under such State's agreement.

(d) For purposes of this section, an individual is treated as an "eligible individual" if he meets the requirements set forth in § 405.205 on the date an agreement covering him is entered into under paragraph (a) of this section (or in the case of individuals covered by virtue of a modification described in paragraph (c) (1) or (2) of this section, as of the date the modification is entered into) or he meets such requirements at any time after such date.

(e) For purposes of this section and § 405.222, an individual is treated as receiving money payments described in paragraph (b) of this section if he receives or the State reports to the Social Security Administration in accordance with prescribed procedures that he is receiving such payments for the month in which the agreement is entered into (or in the case of individuals covered by virtue of a modification of this agreement, for the month the modification is entered into) or for any month occurring thereafter.

(f) For purposes of this section and § 405.222, an individual is treated as eligible to receive medical assistance under the plan of the State approved under title XIX of the Act if, for the month in which the modification described in paragraph (c)(2) of this section is entered into, or for any month occurring thereafter, the State has made a determination (without regard to the retroactivity of such determination) or the State reports to the Social Security Administration in accordance with prescribed procedures that such individual is eligible to receive medical assistance under such plan.

(g) Effective January 1, 1974, an agreement pursuant to paragraph (a) of this section, entered into by any of the fifty States or the District of Columbia will at the request of the State be continued and shall be deemed to have been modified as follows:

(1) Where the State's coverage group as of December 31, 1973, consists of individuals receiving money payments under a plan of the State approved under title XVI of the Social Security Act (see paragraph (b)(1) of this section) and the State has a plan approved under title XIX of the Social Security Act in effect as of December 31, 1973, the State's coverage group shall be deemed to consist of individuals who (i) receive supplemental security income under title XVI of the Social Security Act or State supplementary payments (as the term is used in section 1616(a) of the Social Security Act and in section 212 of Pub. L. 93-66), and (ii) are categorically needy (as the term is used in 42 CFR 448.1) under the plan of such State approved under title XIX of the Social Security Act.

(2) Where the State's coverage group as of December 31, 1973, consists of individuals receiving money payments under the plans of the State approved under titles I, X, XIV, XVI, and part A of title IV of the Social Security Act (see paragraph (b)(2) of this section) and the State has a plan approved under title XIX in effect on December 31, 1973, the State's coverage group shall be deemed to consist of individuals who (i) receive supplemental security income under title XVI of the Social Security Act, or State supplementary payments (as the term is used in section 1616(a) of the Social Security Act and in section 212 of Pub. L. 93-66), or money payments under a plan of the State approved under part A of title IV of the Social Security Act, and (ii) are categorically needy (as the term is used in 42 CFR 448.1) under the plan of such State approved under title XIX of the Social Security Act.

(3) Where a State had an agreement as of December 31, 1973, but it had no plan approved under title XIX of the Social Security Act in effect on December 31, 1973, the State's coverage group shall be deemed to consist of individuals receiving supplemental security income under title XVI of the Social Security Act, State supplementary payments (as the term is used in section 1616(a) of the Social Security Act and in section 212 of Pub. L. 93-66), or money payments under a plan of the State approved under Part A of title IV of the Social Security Act.

(4) For purposes of this section and § 405.222, an individual will be treated as receiving supplemental security income under title XVI of the Social Security Act or State supplementary payments if he receives or the State reports to the Social Security Administration in accordance with prescribed procedures that he receives such income or payments for January 1974 or for any month thereafter.

(5) For purposes of this section and § 405.222, an individual will be treated as categorically needy (as the term is used in 42 CFR 448.1) under a plan of the State approved under title XIX of the Social Security Act, if, for January 1974, or for any month thereafter, he has been determined or the State reports to the Social Security Administration in accordance with prescribed procedures that he has been determined to be categorically needy under such plan.

(h) Where a State's agreement has not been modified, pursuant to a request made by it before 1970, to provide that individuals entitled to monthly benefits under title II of the Social Security Act or entitled to receive an annuity or pension under the Railroad Retirement Act of 1937, as amended, shall be members of the coverage group, such State shall be deemed to have so modified its coverage group, except with respect to individuals receiving money payments under a plan of the State approved under Part A of title IV of the Social Security Act, effective with the month following the effective date of these amendments to regulations.

(i) Except as provided in paragraph (c) of this section, any individual is included in the State's coverage group for any month after August 1972 and before July 1975 if:

(1) For August 1972 he was eligible for money payments under any of the plans of the State included in the coverage group of the State under its agreement under this section, and was eligible for medical assistance under a plan of the State approved under title XIX of the Social Security Act, and was entitled to monthly insurance benefits under title II of the Social Security Act; and (2) for such month after August 1972 and before July 1975 the individual would have been eligible for such money payments had the 20 percent increase in monthly insurance benefits under title II of the Social Security Act provided by Pub. L. 92-336 not been applicable for such individual and, in the case of the fifty States and the District of Columbia after December 31, 1973, had the plan of such state approved under titles I, X, IV, and XVI continued in effect.

[36 FR 16647, Aug. 25, 1971, as amended at 40 FR 43211, Sept. 19, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.220 Coverage period; general.

Payment is made under the supplementary medical insurance plan only for covered expenses incurred during an individual's "coverage period." Subject to the provision that an individual's coverage period continues through the month of death or until such earlier time as his enrollment is terminated, an individual's coverage period begins and terminates as described in §§ 405.221 and 405.223 (a) and (b) or, in the case of an individual enrolled pursuant to a State agreement, in accordance with the provisions of §§ 405.222 and 405.223 (c) and (d).

§ 405.221 Individual enrollment; coverage period beginning date.

An individual's "coverage period" can begin no earlier than July 1, 1966, and begins on a day as determined in accordance with this section (or in the case of an individual enrolled pursuant to a State agreement, in accordance with the provisions of § 405.222):

(a)-(b) [Reserved]

(c) *Enrollment during initial enrollment period; first eligibility after March 1966.* The coverage period of an individual who first meets the eligibility requirements for enrollment after March 1966, and who enrolls during his initial enrollment period (including a deemed initial enrollment period under the provisions of § 405.212(e)), begins on whichever is later, July 1, 1966, or the first day of:

(1) The month in which the eligibility requirements are first met, if he enrolls during the 3 preceding months;

(2) The month following the month in which the eligibility requirements are first met, if he enrolls in the month such requirements are first met;

(3) The third month following the month in which the eligibility requirements are first met, if he enrolls in the month following the month in which such requirements are first met;

(4) The fifth month following the month in which the eligibility requirements are first met, if he enrolls in the second month following the month in which such requirements are first met;

(5) The sixth month following the month in which the eligibility requirements are first met, if he enrolls in the third month following the month such requirements are first met.

Example. An individual first meets the eligibility requirements for enrollment in April of 1967. Therefore, his initial enrollment period runs from January through July 1967. Depending upon the month in which he enrolls, his coverage period will begin as follows:

Enrolls in—Initial enrollment period	Coverage period begins on—
(1) January	April 1 (month eligibility requirements first met).
(2) February	Do.
(3) March	Do.
(4) April	May 1 (month following month eligibility requirements first met).
(5) May	July 1 (third month following month eligibility requirements first met).
(6) June	September 1 (fifth month following month eligibility requirements first met).
(7) July	October 1 (sixth month following month eligibility requirements first met).

(d) *Enrollment during general enrollment period.* The coverage period of an individual who enrolls after his initial or deemed initial enrollment period or reenrolls during a general enrollment period applicable in his case (see §§ 405.213 and 405.214) begins on July 1 following the month in which he so enrolls, or reenrolls.

[36 FR 16647, Aug. 25, 1971, as amended at 40 FR 18166, Apr. 25, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 4429, Feb. 2, 1978]

§ 405.222 Enrollment pursuant to a State agreement; coverage period beginning date.

The coverage period of an individual enrolled pursuant to an agreement with a State under the provisions set forth in § 405.217 begins (without regard to any prior enrollment or termination of enrollment) on whichever of the following is the latest:

(a) July 1, 1966;

(b) The first day of the third month following the month in which the State agreement is entered into (or in the case of individuals covered by virtue of a modification described in § 405.217(c) (1) or (2), as of the first day of the third month following the month such modification is entered into);

(c) The first day of the first month in which he is both an eligible individual (see § 405.205) and a member of the coverage group that is specified in such agreement, except that, if an individual is a member of such group solely by virtue of a modification described in § 405.217(c)(2) (i.e., he does not receive money payments under a plan of the State approved under titles I, X, XIV, XVI or part A of title IV; is not both receiving supplemental security income under title XVI or State supplementary payments and determined to be categorically needy (as the term is used in 42 CFR 448.1) under the plan of the State approved under title XIX; and he is not included in the coverage group by virtue of § 405.217(h)), his coverage period may not begin before the first day of the second month following the month in which he is both an eligible individual and the State has made the determination (without regard to the retroactivity of such determination) that he is eligible to receive medical assistance under the plan of such State approved under title XIX of the Social Security Act; or

(d) Such date as may be specified in the agreement, or, where the individual is covered by virtue of a modification described in § 405.217(c), as may be specified in such modification.

[36 FR 16647, Aug. 25, 1971, as amended at 40 FR 43212, Sept. 19, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.223 Individual enrollments; State enrollments; manner and time of termination of enrollment and coverage period.

Subject to the provision that an individual's coverage period attributable to a State agreement may be terminated only as provided in paragraph (c) of this section and is not subject to termination by the individual, an enrollment and the coverage period may be terminated only as described in this section:

(a) *Individual requests termination.* An individual may at any time after September 1967 notify the Social Security Administration or the Health Care Financing Administration in writing that he no longer wishes to participate in the supplementary medical insurance plan. In such case, his enrollment and coverage period terminate effective with the close of the calendar quarter following the calendar quarter in which such notice is submitted to the Social Security Administration or the Health Care Financing Administration except that:

(1)-(2) [Reserved]

(3) Where an individual entitled to monthly benefits under title II of the Act or to an annuity or pension under the Railroad Retirement Act of 1937, whose coverage attributable to a Federal-State agreement containing the provisions described in § 405.217(c) is terminated or who ceases to be a member of the coverage group before his coverage under such agreement begins, files a written notice with the Social Security Administration or the Health Care Financing Administration before the first day of the fourth month which begins after the date of such termination, his coverage period is terminated effective with the last day of the third month which begins after the date his coverage period under a Federal-State agreement is terminated.

(b) *Nonpayment of premiums.* Enrollment under the supplementary medical insurance plan shall be terminated because of nonpayment of premiums. In such case, an individual's enrollment and coverage period is terminated at such time as is provided in Part 408 of this chapter.

(c) *Enrollees pursuant to State agreement.* In the case of an individual enrolled pursuant to a Federal-State agreement (see § 405.217), the coverage period attributable to the agreement terminates (subject to the provisions of paragraph (d) of this section) on:

(1) The last day of the last month for which he is eligible for inclusion in the coverage group provided that, where the State makes the determination of ineligibility, the State sends notice to the Social Security Administration of such ineligibility within a reasonable time. Such notice shall be given in such form and in accordance with such instructions as prescribed by the Health Care Financing Administration. The notice is considered to be given within a reasonable period of time if the Social Security Administration receives such notice by the 25th

day of the second month after the calendar month in which the individual becomes ineligible for inclusion in the coverage group or, where the individual's State enrollment coverage period began on the basis of a Social Security Administration determination and the State makes the determination of ineligibility after receiving notice from the Social Security Administration through the buy-in data exchange system that the individual is no longer receiving supplemental security income or Federally-administered State supplementary payments, by the 25th day of the second month after the calendar month in which the Social Security Administration so notifies the State. If, however, the Social Security Administration first receives prescribed notice of ineligibility from the State after such reasonable period of time, the individual's coverage attributable to the buy-in agreement will, instead, end on the last day of the second month before the month in which the Social Security Administration receives such notice and, for such purpose, notice received in a calendar month but after the 25th day of that month shall be deemed to have been received in the next following month.

(2) If earlier than paragraph (c)(1) of this section, whichever of the following first occurs:

(i) The last day of the month preceding the first month in which the individual became entitled to monthly benefits under title II of the Social Security Act (see Subpart D of 20 CFR Part 404) or to an annuity or pension under the Railroad Retirement Act of 1937 without regard to the retroactivity of such entitlement unless the State agreement provides for the inclusion of such individuals entitled to such benefits in the coverage group, or

(ii) The last day of the month as of which the State agreement is terminated, or

(iii) The last day of the month in which he dies, or

(iv) If he is under 65, the last day of the last month for which he is entitled to hospital insurance benefits.

(d) *Continuation of enrollees' coverage period pursuant to State agreements.* Notwithstanding the provisions of paragraph (c) of this section, if an individual's coverage pursuant to enrollment under a State agreement is terminated under the provisions of paragraph (c) of this section, such individual is deemed to have enrolled for supplementary medical insurance benefits in the initial enrollment period described in § 405.212 and his coverage period continues until terminated for his failure to pay premiums or by his written notice to the Social Security Administration or the Health Care Financing Administration that he wishes to terminate his supplementary medical insurance coverage, as provided in paragraphs (a) and (b) of this section. An individual who is enrolled under a State agreement but who ceases to be a member of the coverage group before his coverage begins is also deemed to have so enrolled and his coverage as an individual begins on the date his coverage under the agreement would have begun had he continued in the coverage group.

(e) *Termination of hospital insurance before individual attains age 65.* If an enrollee's hospital insurance entitlement terminates before the month in which he attains age 65, his medical insurance coverage period, if it has not previously ended pursuant to paragraph (a) or (b) of this section, will terminate on the same date as his hospital insurance entitlement (see § 405.103(b)).

[36 FR 16647, Aug. 25, 1971, as amended at 40 FR 18166, Apr. 25, 1975; 40 FR 43212, Sept. 19, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 4429, Feb. 2, 1978; 52 FR 48123, Dec. 18, 1987]

§ 405.226 Equitable relief for individual whose enrollment rights have been prejudiced by government misrepresentation, inaction or error.

Notwithstanding any other provision of this subpart or Part 408 of this chapter, in any case where it is established that an individual's enrollment or nonenrollment in the supplementary medical insurance plan or in the hospital insurance plan pursuant to section 1818 of the Social Security Act, is unintentional, inadvertent, or erroneous, and is the result of the error, misrepresentation or inaction of an officer, employee, or agent of the Federal Government or its instrumentalities, the Social Security Administration may provide equitable relief to correct or eliminate the effects of such prejudicial misrepresentation, inaction, or error. Such equitable relief may include, but is not limited to, designation of a special initial or subsequent enrollment period or coverage period, or adjustment in premiums, or any combination of these measures.

[39 FR 2757, Jan. 24, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 52 FR 48123, Dec. 18, 1987]

Subpart C—Exclusions, Recovery of Overpayment, Liability of a Certifying Officer and Suspension of Payment

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1861, 1862, 1866, 1870, 1871 and 1879 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395x, 1395y, 1395cc, 1395gg, 1395hh, and 1395pp) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

GENERAL PROVISIONS

§ 405.301 Scope of subpart.

Sections 405.308 to 405.320 describe certain exclusions from coverage applicable to hospital insurance benefits (Part A of Title XVIII) and supplementary medical insurance benefits (Part B of Title XVIII). The exclusions in this subpart are applicable in addition to any other conditions and limitations in this Part 405 and in Title XVIII of the Act. Sections 405.322 to 405.325 relate to exclusion of services covered under automobile medical, no-fault, or liability insurance. Sections 405.326 to 405.329 relate to limitations on payment for services to ESRD beneficiaries who are covered under employer group health plans. Sections 405.330 to 405.336 relate to payments for expenses for certain items or services otherwise excluded from coverage. Sections 405.340 to 405.344 relate to limitation on payment for services furnished to employed aged and their spouses. Sections 405.350 to 405.359 relate to the adjustment or recovery of an incorrect payment, or a payment made under section 1814(e) of Part A of Title XVIII of the Act. Sections 405.370 to 405.373 relate to the suspension of payment to a provider of services or other supplier of services where there is evidence that such provider or supplier had been or may have been overpaid. Section 405.374 relates to the collection and compromise of claims for overpayments. Section 405.375 relates to the withholding of Medicare payments to recover Medicaid overpayments. Section 405.376 relates to the charging and payment of interest on overpayments and underpayments to providers and suppliers, and physicians and other practitioners.

[48 FR 39808, Sept. 1, 1983, as amended at 50 FR 19688, May 10, 1985; 50 FR 35687, Sept. 3, 1985; 51 FR 6235, Feb. 21, 1986]

§ 405.308 Limitations on charges to beneficiaries.

(a) *Prospective payment hospitals.* A hospital receiving payment under the prospective payment system for a covered hospital stay may charge a beneficiary for items and services excluded from coverage only as described in § 412.42 of this chapter.

(b) *Hospitals participating in State reimbursement control systems or demonstration projects.* A hospital receiving payment for a covered hospital stay under either a State reimbursement control system approved under 1886(c) of the Act or a demonstration project authorized under section 402(a) of Pub. L. 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Pub. L. 92-603 (42 U.S.C. 1395b-1 (note)) and that would otherwise be subject to the prospective payment system may charge a beneficiary for noncovered services as follows:

(1) For the custodial care and medically unnecessary services described in § 412.42(c) of this chapter, after the conditions of § 412.42 (c)(1) through (c)(4) are met; and

(2) For all other services in accordance with the applicable rules described in Part 489 of this chapter.

[50 FR 35687, Sept. 3, 1985]

§ 405.310 Particular services excluded from coverage.

The following services are excluded from coverage.

(a) *Routine physical checkups such as—*

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptom, complaint, or injury; or

(2) Examinations required by insurance companies, business establishments, government agencies, or other third parties.

(b) *Eyeglasses or contact lenses, except for* post-surgical lenses customarily used during convalescence from eye surgery in which the lens of the eye was removed (e.g., cataract surgery); or prosthetic lenses for patients who lack the lens of the eye because of congential absence or surgical removal.

(c) *Eye examinations* for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive error only and procedures performed in the course of any eye examination to determine the refractive state of the eyes, without regard to the reason for the performance of the refractive procedures. Refractive procedures are excluded even when performed in connection with otherwise covered diagnosis or treatment of illness or injury.

(d) *Hearing aids* or examinations for the purpose of prescribing, fitting, or changing hearing aids.

(e) *Immunizations, except for—*

(1) Vaccinations or inoculations directly related to the treatment of an injury or direct exposure such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenom sera, or immune globulin; and

(2) Pneumococcal vaccinations that are reasonable and necessary for the prevention of illness.

(f) *Orthopedic shoes* or other supportive devices for the feet, *except when* shoes are integral parts of leg braces.

(g) *Custodial care, except as necessary* for the palliation or management of terminal illness, as provided in Part 418 of this chapter. (Custodial care is any care that does not meet the requirements for coverage as posthospital SNF care as set forth in §§ 409.30 through 409.35 of this chapter.)

(h) *Cosmetic surgery* and related services, *except* as required for the prompt repair of accidental injury or to improve the functioning of a malformed body member.

(i) *Dental services* in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth, *except for* inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(1) The individual's underlying medical condition and clinical status; or

(2) The severity of the dental procedures.[1]

(j) *Personal comfort services, except* as necessary for the palliation or management of terminal illness as provided in Part 418 of this chapter. The use of a television set or a telephone are examples of personal comfort services.

(k) *Any services that are not reasonable and necessary* for one of the following purposes:

(1) For the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(2) In the case of hospice services, for the palliation or management of terminal illness, as provided in Part 418 of this chapter.

(3) In the case of pneumococcal vaccine, for the prevention of illness.

(l) *Foot care*—(1) *Basic rule.* Except as provided in paragraph (l)(2) of this section, any services furnished in connection with the following:

(i) *Routine foot care,* such as the cutting or removal of corns, or calluses, the trimming of nails, routine hygienic care (preventive maintenance care ordinarily within the realm of self care), and any services performed in the absence of localized illness, injury, or symptoms involving the feet.

(ii) *The evaluation or treatment of subluxations of the feet,* regardless of underlying pathology. (Subluxations are structural misalignments of the joints, other than fractures or complete dislocations, that require treatment only by nonsurgical methods.)

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[1] Paragraph (i)(2) is effective for services furnished after June 30, 1981.

(iii) *The evaluation or treatment of flattened arches* (including the prescription of supportive devices) regardless of the underlying pathology.

(2) *Exceptions.* (i) Treatment of warts is not excluded.

(ii) Treatment of mycotic toenails may be covered if it is furnished no more often than every 60 days or the billing physician documents the need for more frequent treatment.

(iii) The services listed in paragraph (l)(1) of this section are not excluded if they are furnished—

(A) As an incident to, at the same time as, or as a necessary integral part of a primary covered procedure performed on the foot; or

(B) As initial diagnostic services (regardless of the resulting diagnosis) in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.

(m) *Services to hospital inpatients*—(1) *Basic rule.* Except as provided in paragraph (m)(2) of this section, any service furnished to an inpatient of a hospital by an entity other than the hospital, unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's inpatients.[2]

(2) *Exception.* Physicians' services that meet the criteria of § 405.550(b) for payment on a reasonable charge basis, and services of an anesthetist employed by a physician that meet the conditions of § 405.553(b)(4), are not excluded.

[50 FR 33030, Aug. 16, 1985, as amended at 51 FR 41336, Nov. 14, 1986; 53 FR 38526, Sept. 30, 1988]

§ 405.310-1 Nonreimbursable expenses: conclusive effect of PRO determinations on claims payment.

If a PRO has assumed review responsibility in accordance with the applicable provisions of Part 466 of this chapter for items and services furnished to a beneficiary, no Federal funds appropriated under Title XVIII of the Act shall be used (directly or indirectly) for the payment of any claim for those items and services unless the conditions of Part 466, Subpart C of this chapter are met.

[44 FR 16397, Mar. 19 1979, as amended at 51 FR 43197, Dec. 1, 1986]

GENERAL EXCLUSIONS

§ 405.311 Nonreimbursable expenses; individual has no legal obligation to pay for items or services.

Payment may not be made under Title XVIII of the Act for expenses incurred for items or services for which the individual who is furnished such items or services has no legal obligation to pay, and which no other person (by reason of the individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for. For example, no payment may be made for items or services, such as a chest X-ray, that are rendered free of charge by health organizations without regard for the individual's ability to pay. This exclusion does not prevent payment for items or services furnished by a group health prepayment plan to a member of the plan. Neither does it apply to items or services paid for by a governmental entity (with respect to such items or services, see § 405.312).

§ 405.311a Nonreimbursable expenses; items or services furnished by a Federal provider of services or other Federal agency.

Payment may not be made for expenses incurred for any items or services that are furnished by a Federal provider of services or other Federal agency, except that:

(a) Payment may be made for emergency hospital services if the conditions in Subpart G of Part 424 of this chapter of this chapter are met;

(b) Payment may be made to a participating Federal provider which has been determined by the Secretary to be providing services to the public generally as a community institution or agency; and

(c) Payment may be made for items and services furnished by participating hospitals and skilled nursing facilities of the Indian Health Service, notwithstanding § 405.311.

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[2] This exclusion was effective as of October 1, 1983.

[44 FR 2593, Jan. 12, 1979, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6647, Mar. 2, 1988]

§ 405.311b Nonreimbursable expenses; items or services which a provider or other person is obligated to furnish at public expense under a law of, or contract with, the United States.

Payment may not be made for items or services that a provider of services or other person (other than a hospital or skilled nursing facility of the Indian Health Service) is obligated by a law of, or contract with, the United States to furnish at public expense.

[44 FR 2593, Jan. 12, 1979]

§ 405.312 Nonreimbursable expenses; items or services paid for by governmental entity.

Payment may not be made under Title XVIII of the Act for expenses incurred for items or services that are paid for directly or indirectly by a governmental entity, except:

(a) Payment may be made for items or services furnished under a health insurance plan established for employees of the governmental entity.

(b) Payment may be made for items or services furnished an individual under a program based on one of the titles of the Social Security Act.

(c) Payment may be made for items and services furnished an individual in or by a participating hospital operated by a State or local governmental entity, where such hospital is a general or special hospital serving the general community, including a mental or tuberculosis hospital or a hospital for treatment of infectious disease.

(d) Payment may be made for items and services paid for by a State or local governmental entity and furnished an individual as a means of controlling infectious diseases or because of the individual's medical indigency, whether or not such services are furnished in a hospital.

(e) Payment may be made for items and services furnished by participating hospitals and skilled nursing facilities of the Indian Health Service.

(f) Payment may be made for items and services furnished by a public or private health facility which receives United States Government funds under a Federal program which provides support to facilities which furnish health care services (other than a Federal provider of services): *Provided*, The facility receiving such Federal support customarily seeks reimbursement for items and services not covered under Title XVIII of the Social Security Act, from all resources available for the health care of its patients, e.g., private insurance, patients' cash resources, etc. Payments that are made for such items and services covered under supplementary medical insurance shall be subject to the individual's deductible and shall not exceed 80 percent of charges related to reasonable costs that the facility incurs in providing the items and services. The facility's charges to the individual must not exceed 20 percent of such charges plus any unsatisfied deductible amounts and charges for noncovered services.

(g) Payment may be made in other cases as specified by the Secretary under authority of section 1862(a)(3) of the Act.

[31 FR 13534, Oct. 20, 1966, as amended at 36 FR 6943, Apr. 13, 1971. Redesignated at 42 FR 52826, Sept. 30, 1977, and further amended at 44 FR 2593, Jan. 12, 1979]

§ 405.313 Nonreimbursable expenses; items or services not provided in the United States.

Payment may not be made under Title XVIII of the Act for expenses incurred for items or services which are not provided within the United States (that is, the States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa) except:

(a) Inpatient hospital services furnished outside the United States in accordance with the provisions of Subpart H of Part 424 of this chapter, and

(b) Effective with admissions occurring after December 31, 1972, payment may be made on the basis of an itemized bill for physician and ambulance services furnished an individual in conjunction with such covered inpatient hospital services but only for the period during which such inpatient hospital services were furnished.

[39 FR 1750, Jan. 14, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 6647, Mar. 2, 1988]

§ 405.314 Nonreimbursable expenses; items or services required as a result of war.

Payment may not be made under Title XVIII of the Act for expenses incurred for items or services which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage for hospital insurance benefits or supplementary medical insurance benefits.

§ 405.315 Nonreimbursable expenses; charges imposed by immediate relatives or members of beneficiaries' household.

Payment on a reasonable charge basis may not be made under Part B of Title XVIII of the Act (see Subpart B of this part) for expenses incurred by an individual, if such expenses constitute charges (including the professional component of services of hospital-based physicians—see § 405.480 et seq.) imposed by physicians or other persons who are immediate relatives of such individual or members of his household, to the extent that such charges exceed the actual costs incurred by such physicians or other persons in procuring items furnished such individual.

(a) Any person who has any of the following degrees of relationship to any other person is an "immediate relative":

(1) Husband and wife; (2) natural parent, child, and sibling; (3) adopted child and adoptive parent; (4) stepparent, stepchild, stepbrother, and stepsister; (5) father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, and sister-in-law; (6) grandparent and grandchild.

(b) The term "members of his household" means those persons sharing a common abode as part of a single family unit, including those related by blood, marriage, or adoption as well as domestic employees and others who live together as part of this family unit, but not including a mere roomer or boarder.

(c) The exclusion refers to the person imposing the charges, who might not be the person rendering the services. For example, where the charges are imposed by a:

(1) Physician or other practitioner, the exclusion would apply to charges imposed for personal services, if the physician or other practitioner has the excluded relationship to the beneficiary.

(2) Partnership, the exclusion would apply only if all of the partners have the excluded relationship to the beneficiary.

(3) Corporation, the exclusion would not apply, regardless of the beneficiary's relationship to the directors, officers, stockholders of the corporation, or person rendering the services.

(4) Individual proprietorship, the exclusion applies if the individual who owns and operates the business has the excluded relationship to the beneficiary.

[31 FR 13534, Oct. 20, 1966, as amended at 33 FR 9767, July 6, 1968. Redesignated at 42 FR 52826, Sept. 30, 1977]

EXCLUSION OF SERVICES COVERED UNDER WORKERS' COMPENSATION

§ 405.316 Nonreimbursable expenses; payment for services made under workmen's compensation law.

(a) Payment may not be made under Title XVIII of the Act with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made, under a workmen's compensation law or plan of the United States or a State. However, where payment for any item or service may not be made by workmen's compensation because furnished by a source not authorized to provide such item or service under the workmen's compensation program, payment for such item or service may be made under Title XVIII of the Act if otherwise covered. See § 405.317(d), (e), and (f) for situations in which payment may be made under Title XVIII for services for which payment is not made under the workmen's compensation award.

(b) Any payment under Title XVIII of the Act with respect to any item or service shall be made on the condition that repayment will be made to the supplementary medical insurance trust fund or the hospital insurance trust fund, as appropriate, if information is received that payment for the item or service has been made under a workmen's compensation law or plan of the United States or a State.

(c) For purposes of this exclusion, a workmen's compensation plan or system of the United States includes the workmen's compensation plans of the 50 States, the District of Columbia, and Puerto Rico, as well as the systems provided under the Federal Employees' Compensation Act and the Longshoremen's and Harbor Workers' Compensation Act.

[31 FR 13534, Oct. 20, 1966, as amended at 38 FR 13637, May 24, 1973. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.317 Effect of workmen's compensation payment.

(a) *Spell of illness.* A period of inpatient hospital or extended care services for which Title XVIII payment may not be made because of § 405.316(a) will be considered in determining whether a spell of illness has begun or has ended (see section 1861(a) of the Act).

(b) *Expenses paid by workmen's compensation.* Services for which payment may not be made because of § 405.316(a) shall not be considered in determining:

(1) The 90-day limitation on inpatient hospital services in each spell of illness (see § 405.110(a)(1)).

(2) The additional 60 lifetime reserve days of inpatient hospital services (see § 405.110(a)(2)).

(3) The 100-day limitation on posthospital extended care services in each spell of illness (see § 405.120(b)).

(4) The 190-day lifetime limitation for inpatient psychiatric hospital services (see § 405.110(d)).

(5) The 100 home health visits limitation under Part A or Part B of Title XVIII (see § 405.130).

(6) The days for which payment for inpatient hospital services or posthospital extended care services is reduced by the applicable deductible or coinsurance amount (see §§ 405.113, 405.115, and 405.124).

(c) *Deductibles and coinsurance.* Payments made under workmen's compensation cannot be counted toward the deductibles or coinsurance provisions of Title XVIII. Thus, if an individual is hospitalized twice in the same spell of illness and the first hospitalization is completely paid for under workmen's compensation, the inpatient hospital deductible would apply to the second hospitalization. In the same way, medical expenses otherwise reimbursable under Part B must first be reduced by any workmen's compensation payment before applying the deductible and coinsurance provisions.

(d) *Limitation in workmen's compensation law on number of days of care or total amount payable.* Certain workmen's compensation programs specify limits on the number of days of care for which payment can be made or the total amount that can be paid for medical care under workmen's compensation with respect to a compensable injury. Services provided after these limits have been reached may be paid for under Title XVIII of the Act subject to the deductible and coinsurance requirements. Where services have been furnished after such workmen's compensation limits have been reached, the following rules apply in determining the services for which payment may be made under Title XVIII of the Act:

(1) The workmen's compensation payment for such services shall be allocated at the normal workmen's compensation rate of payment to those services furnished first in time until the workmen's compensation benefits are exhausted. Any services otherwise covered under Title XVIII of the Act and not paid for under workmen's compensation after such allocation has been made may be paid for under Title XVIII, subject to the program provisions as to reasonable cost and to any applicable deductible or coinsurance amounts.

Example. A beneficiary received 60 days of inpatient hospital services for an injury that is compensable under workmen's compensation. This is the beneficiary's first hospital stay in the spell of illness. The hospital's customary all-inclusive charge for inpatient services in semiprivate accommodations is $50 per day and the workmen's compensation payment is made on the basis of customary charges. Under the workmen's compensation law of the State, however, $1,500 is the maximum that can be paid for these services.

The $1,500 workmen's compensation payment would be allocated to the first 30 days of services and the remaining 30 days of that hospital stay would be reimbursable under Title XVIII of the Act. The hospital would receive under Title XVIII its full reasonable costs for the remaining 30 days less the inpatient hospital deductible. The beneficiary would be charged with 30 days utilization of inpatient hospital services in that spell of illness.

(2) Where the workmen's compensation payment for the last day to which it can be applied is less than the cost of the services provided on that day, payment may be made under Title XVIII of the Act for the difference between the workmen's compensation payment and the reasonable cost of the services furnished subject to any applicable deductible or coinsurance amounts. Such a day would be charged to the beneficiary's utilization record (except where lifetime reserve days are involved).

Example. A beneficiary received 45 days of inpatient hospital services for an injury that is compensable under workmen's compensation. This is the beneficiary's first hospital stay in the spell of illness. The hospital's customary all-inclusive charge for inpatient services in semiprivate accommodations is $60 per day and the workmen's compensation payment is made on the basis of customary charges. Under the workmen's compensation law of the State, however, $1,525 is the maximum that can be paid for these services.

The $1,525 workmen's compensation payment would be allocated as follows: $1,500 to the first 25 days of service and $25 towards the 26th day. The hospital would receive under Title XVIII of the Act its full reasonable costs for the last 20 days less the inpatient hospital deductible and the $25 paid by workmen's compensation for the 26th day. The beneficiary would be charged with 20 days utilization of inpatient hospital services in that spell of illness.

(e) *Patient received semiprivate accommodations but workmen's compensation paid only for ward accommodations*—(1) *Workmen's compensation pays customary charges for ward accommodations.* Where a beneficiary is furnished semiprivate accommodations but the workmen's compensation plan pays the hospital's customary charges for ward accommodations, payment under Title XVIII of the Act is limited to the amount by which the hospital's reasonable cost of furnishing semiprivate accommodations exceeds the hospital's customary charges for ward accommodations at the time of the stay.

(2) *Workmen's compensation pays special rate for ward accommodations.* Where a beneficiary is furnished semiprivate accommodations but the workmen's compensation plan pays only for ward accommodations at a special rate which is less than the hospital's customary charge for ward accommodations, it is assumed, in the absence of evidence to the contrary, that the special rate paid by the workmen's compensation program is deemed payment in full for ward accommodations under the State workmen's compensation law. In such case, payment under Title XVIII of the Act is limited to the amount by which the hospital's reasonable cost of furnishing semiprivate accommodations exceeds the hospital's customary charges for ward accommodations at the time of the stay. In cases, however, where the special rate paid by the workmen's compensation program is not deemed payment in full for ward accommodations, payment under Title XVIII is limited to the amount by which the reasonable cost of semiprivate accommodations exceeds the workmen's compensation payment.

Example. A beneficiary was furnished semiprivate accommodations at X Hospital for an illness that is covered under the workmen's compensation program. The workmen's compensation program pays only for ward accommodations ($50 per day). X Hospital's reasonable cost of furnishing semiprivate accommodations is $52. X Hospital is entitled to receive $2 per day reimbursement under Title XVIII (the $52 per day reasonable cost of semiprivate accommodations less the $50 per day paid by workmen's compensation).

If the workmen's compensation program paid a special rate of $40 per day for ward accommodations, which amount is deemed payment in full for ward accommodations under State law, X Hospital would still be entitled to receive an additional $2 per day reimbursement under Title XVIII (the $52 per day reasonable cost of semiprivate accommodations less the $50 per day customary charge for ward accommodations).

(3) *Utilization days charged.* Where a beneficiary is furnished semiprivate accommodations and the workmen's compensation plan pays only for ward accommodations (at either the hospital's customary rate for ward accommodations or at a special rate which is less than the hospital's customary charge for such accommodations), the beneficiary is charged with utilization on a pro rata basis (based on the proportion which the payment made under Title XVIII of the Act bears to the total payment for the period during which these accommodations were furnished).

(f) *Workmen's compensation does not pay for certain ancillary services.* Sometimes an individual who is receiving inpatient hospital services for a work injury which is covered under workmen's compensation may also receive ancillary services for a condition which is not work-related, e.g., laboratory services or medication for a preexisting condition. In such cases, if the workmen's compensation plan pays for all of the hospital expenses related to the work injury (including the room and board charges) but not for the ancillary services which are not work-related, Title XVIII benefits may be paid for such ancillary services, subject to the Part A deductible or the Part B deductible and coinsurance provisions. The beneficiary would not be charged with utilization for the days on which these services were received.

Example. An individual was hospitalized for 20 days due to a work-related injury. His bill included $1,100 in charges for room and board and other items and services related to the work injury and $65 in laboratory and medication charges for services in connection with a preexisting condition. Workmen's compensation paid the $1,100 in charges for services related to the work injury, but did not pay the $65 in laboratory and medication charges for the preexisting condition. Since the $65 in charges for laboratory services and medication are not covered under workmen's compensation. Title XVIII benefits may be paid for such expenses subject to any applicable deductible and coinsurance provisions. The individual would not be charged with utilization for the day or days on which the services were received.

[38 FR 13637, May 24, 1973. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.318 Responsibility of the individual concerning workmen's compensation payment.

The individual is responsible for taking whatever action is necessary to obtain payment under workmen's compensation where payment under that system can reasonably be expected. Failure to take proper and timely action under such circumstances will preclude payment under Title XVIII of the Act to the extent that payment could have been expected under workmen's compensation if such action had been taken. Thus, so long as the facts indicate a reasonable expectation that payment may be made under a workmen's compensation statute, the individual must exhaust his remedies under that system before any payment may be made under Title XVIII of the Act, except as specified in § 405.319(b). Where the time limit for taking action under workmen's compensation has expired and the intermediary determines that payment under workmen's compensation could reasonably have been expected if timely action had been taken, payment under Title XVIII of the Act will be precluded to the extent that the disease or injury for which Title XVIII payment is claimed would be compensable under workmen's compensation had timely action been taken. However, in the event a workmen's compensation claim is subsequently filed and denied solely for reasons other than the delay in filing, the decision denying Title XVIII benefits will be reopened, and, if otherwise appropriate, the Title XVIII claim will be allowed.

[38 FR 13638, May 24, 1973. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.319 Responsibility of intermediary where there is a possibility of workmen's compensation coverage.

(a) *Investigation of possible workmen's compensation coverage.* Where it appears that a claim submitted to an intermediary is for services furnished with respect to a disease or injury which may be compensable under a State or Federal workmen's compensation law or plan, the intermediary will undertake an investigation to ascertain the extent to which payment under Title XVIII of the Act may be precluded.

(b) *Conditional payment in appealed workmen's compensation cases.* If a Title XVIII beneficiary, his employer, or a workmen's compensation carrier is appealing a decision as to the compensability under workmen's compensation of services for which benefits could be paid under Title XVIII in the absence of such compensability, conditional Title XVIII payments may be made (if otherwise appropriate) pending a final decision on the workmen's compensation claim provided:

(1) The intermediary obtains a subrogation agreement signed by the following:

(i) The workmen's compensation carrier or State Workmen's Compensation Commission or agency; and

(ii) The individual or his qualified representative; and

(iii) The provider, physician, or other person who furnished the services for which payment is to be made.

(2) The subrogation agreement provides that the workmen's compensation carrier or State Workmen's Compensation Commission or agency:

(i) Will notify the intermediary promptly when a final decision is reached on the workmen's compensation claim; and

(ii) Will reimburse the intermediary the amount of the conditional payment made under Title XVIII up to the full amount of the workmen's compensation award, in the event that the services are found to be compensable.

[38 FR 13638, May 24, 1973. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.320 Effect of lump-sum settlement and final release.

Where a lump-sum settlement and final release of a workmen's compensation claim has been entered into and approved by the workmen's compensation board or agency, payment may be made under Title XVIII of the Act for expenses incurred for covered services to the extent that such expenses cannot reasonably be deemed to have been reimbursed under the settlement. Therefore, where under the State law the signing of a final release of all rights under the workmen's compensation claim forecloses the possibility of further workmen's compensation benefits, medical expenses incurred thereafter are reimbursable under Title XVIII, if otherwise covered, insofar as such medical expenses were not contemplated by and incorporated into the settlement.

[38 FR 13639, May 24, 1973. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.321 Apportionment of a lump-sum compromise settlement of a workmen's compensation claim.

(a) *General.* Where an individual receives a lump-sum payment as a compromise settlement of a workmen's compensation claim, which has been approved by the workmen's compensation agency, in accordance with the requirements of the State law, such payment shall be deemed a workmen's compensation payment for purposes of Title XVIII, even if the settlement agreement stipulates that there is no liability under the workmen's compensation law.

(b) *Determining amount of compromise settlement attributable to medical and hospital expenses.* Where the compromise settlement specifies the items of medical expense covered by the lump-sum payment and has given reasonable recognition to the income replacement element, the apportionment so made shall be deemed conclusive and Title XVIII payments may not be made for the same items of medical expense. However, where the settlement does not give recognition to both elements of a workmen's compensation award or does not apportion the sum granted, the portion of the workmen's compensation compromise settlement to be considered as payment for medical and hospital expenses will be calculated as follows:

(1) Determine the ratio which the amount awarded as a compromise settlement (less the reasonable and necessary costs incurred in procuring the settlement) bears to the commuted value of the total amount which would

have been payable under workmen's compensation if the claim had not been compromised.

(2) Multiply the total medical and hospital expenses incurred as a result of the injury or disease up to the date of the settlement by such ratio. The product will be deemed to be the amount of the workmen's compensation settlement intended as payment for medical and hospital expenses.

Example. As the result of an injury which was compensable under the State workmen's compensation law an individual suffered a loss of income and incurred hospital and medical expenses for which the commuted value of the total workmen's compensation payment would have been $7,200 had the case not been compromised. The medical and hospital expenses amounted to $6,000. The workmen's compensation carrier made a settlement with the beneficiary under which it paid $2,400 in toto. A separate award was made for legal fees. Since the workmen's compensation compromise settlement was for one-third of the amount which would have been payable under workmen's compensation had the case not been compromised 2400/7200 (=⅓), the workmen's compensation compromise settlement is deemed to have paid for one-third of the total medical and hospital expenses (⅓×$6,000 =$2,000).

(c) *Determination of amount of medical expenses reimbursable under Title XVIII.* The amount of the workmen's compensation award deemed as payment for medical and hospital expenses (obtained in paragraph (b) of this section) is applied at the prevailing workmen's compensation rate of payment in that jurisdiction, first to those medical and hospital services covered under workmen's compensation but not covered under Title XVIII of the Act, then to expenses covered under workmen's compensation and under Part B, and last to expenses covered under workmen's compensation and under Part A. Any remaining medical and/or hospital expenses incurred up to the date of settlement and all medical and/or hospital expenses incurred after the date of settlement shall be deemed not reimbursed under workmen's compensation and therefore reimbursable under Title XVIII of the Act.

Example. In the example in paragraph (b) of this section, the $6,000 in hospital and medical expenses included $3,400 in hospital services reimbursable under Part A, $2,100 in expenses for which payment would have been available under Part B, and $500 in expenses for services not reimbursable under Title XVIII. The amount of Title XVIII benefits payable would be figured as follows: The $2,000 of the compromise workmen's compensation settlement considered as payment for medical and hospital expenses would be applied first to the $500 in noncovered services; the remaining $1,500 would be applied to the $2,100 in expenses for which payment would have been available under Part B. The remaining $600 of such expenses would be reimbursable under Part B of Title XVIII and all of the $3,400 in hospital expenses would be reimbursable under Part A, subject to the regular deductible and coinsurance requirements. It is assumed in this example that the expenses specified above as incurred by the individual are the amounts which would be paid by the workmen's compensation carrier for such services. If this is not the case, the services should be charged against the lump-sum payment at the usual workmen's compensation rate. No Title XVIII payment will be made for any items so charged.

[38 FR 13639, May 24, 1973. Redesignated at 42 FR 52826, Sept. 30, 1977]

EXCLUSION OF SERVICES COVERED UNDER AUTOMOBILE MEDICAL, NO-FAULT, OR LIABILITY INSURANCE

§ 405.322 Services covered under automobile medical or no-fault insurance, or any liability insurance: General provisions.

(a) *Applicability.* The provisions of this section and of §§ 405.323 through 405.325 are applicable to services required because of accidents that occurred on or after December 5, 1980.

(b) *Definitions.* As used in this section, and §§ 405.323 through 405.325—

"*Automobile*" means any self-propelled land vehicle of a type that must be registered and licensed in the State in which it is owned.

"*Automobile medical or no-fault insurance*" means automobile insurance (including self-insured plans) that pays for all or part of the medical expenses for injuries sustained in the use, occupancy, or operation of an automobile, regardless of who may have been responsible for causing the accident. (This insurance is sometimes called "medical payments coverage" "personal injury protection", or "medical expense coverage".)

"Liability insurance" means insurance (including a self-insured plan) that provides payment based on legal liability for injury to persons or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance.

"Self-insured plan" means a plan under which an entity (or an individual) is authorized by State law to carry its own risk instead of insuring itself with a carrier.

"Uninsured motorist insurance" means insurance under which the policyholder's insurer will pay for damages caused by a motorist who has no automobile liability insurance or who carries less than the amount of insurance required by law or is underinsured.

(c) *Exclusion from Medicare payment.* (1) Medicare payment may not be made for any services to the extent that payment has been made or can reasonably be expected to be made under automobile medical or no-fault insurance or under any liability insurance policy or plan (including a self-insured plan).

(2) If payment was erroneously made by HCFA for services covered under automobile medical or no-fault insurance, or paid for under liability insurance, the payment is subject to recovery.

(d) *Services paid for under automobile or liability insurance.* Effective for services furnished on or after December 5, 1980, if payment is made under automobile medical or no-fault insurance or any liability insurance—

(1) Except as provided in paragraph (d)(2) of this section. Medicare payment will be denied or, if already made, will be recovered from the provider, supplier, or beneficiary who received the Medicare payment.

(2) *Exception.* HCFA will not recover the Medicare payment if the insurance payment was actually received by the beneficiary before June 6, 1983.

(e) *Waiver of recovery.* HCFA may waive recovery action if the probability of recovery or the amount involved does not warrant pursuit of the claim.

[48 FR 14809, Apr. 5, 1983]

§ 405.323 Special provisions: Services for which payment can reasonably be expected under automobile medical or no-fault insurance.

(a) *Effective date.* This section is effective for services furnished on or after June 6, 1983.

(b) *Automobile medical or no-fault benefits excluded or limited for medicare beneficiaries.* Except as specified in paragraph (c) of this section payment may not be made for services covered under an automobile medical or no-fault insurance policy or plan even though State law or the insurance policy or plan states that its benefits are secondary to Medicare's or otherwise excludes or limits its payments if the injured party is also entitled to Medicare benefits.

(c) *Conditional payment in contested or otherwise delayed cases.* (1) A conditional Medicare payment may be made under any of the following circumstances:

(i) The beneficiary, or the provider or supplier, has filed a claim for automobile medical or no-fault insurance benefits but, because the claim is contested by the insurer or for any other reason, there will be substantial delay in making insurance payments.

(ii) The beneficiary failed to file a claim for automobile medical or no-fault insurance benefits because of physical or mental incapacity.

(2) HCFA may as a prerequisite for the conditional payment, require the beneficiary to authorize it to pursue the beneficiary's rights against the insurer if the beneficiary does not, and to promise to cooperate in HCFA's action.

(3) If a conditional Medicare payment is made, the following rules apply:

(i) If the beneficiary receives payment from the automobile medical or no-fault insurer, he or she must reimburse Medicare up to the amount of the Medicare payment.

(ii) If the provider or supplier receives payment from the automobile medical or no-fault insurer, it must reimburse Medicare up to the amount of the Medicare payment.

(iii) If, for any reason, payment is not received from the insurer, HCFA may bring an action against the insurer to recover the amounts due under the statute. The beneficiary must cooperate in HCFA's action

(4) The amount of recovery under paragraph (c)(3)(iii) of this section will not exceed the amount of the conditional payment.

(5) At the time the conditional payment is made, the Medicare intermediary or carrier will notify the beneficiary or his or her representative of the obligation to refund the conditional payment. However, failure to send notice does not relieve the beneficiary of the obligation to refund the conditional payment, as required by paragraph (c)(3)(i) of this section.

[48 FR 14810, Apr. 5, 1983]

§ 405.324 Special provisions: Services for which payment can reasonably be expected under liability insurance.

(a) *Conditional Medicare payment.* (1) If HCFA has information that services for which Medicare benefits have been claimed are for treatment of an injury or illness that was allegedly caused by another party and that the beneficiary has filed, or has the right to file, a liability claim against the other party, a conditional Medicare payment may be made.

(2) HCFA may, as a prerequisite for conditional payment, require the beneficiary to authorize it to pursue the beneficiary's rights against the insurer or the responsible party if the beneficiary does not, and to promise to cooperate in HCFA's action.

(3) If a conditional Medicare payment is made, the following rules apply:

(i) If the beneficiary receives payment from an insurance carrier or self-insured party, he or she must reimburse Medicare up to the amount of the Medicare payment.

(ii) If the provider or supplier receives payment from the insurance carrier or self-insured party, it must reimburse Medicare up to the amount of the Medicare payment.

(iii) If payment is not received from the insurer or the responsible party, HCFA may bring an action against the insurer or the responsible party, and the beneficiary must cooperate in HCFA's action.

(4) The amount of recovery under paragraph (a)(3)(iii) of this section will not exceed the amount of the conditional payment.

(5) At the time the conditional Medicare payment is made, the Medicare intermediary or carrier will notify the beneficiary or his or her representative of the obligation to refund the conditional payment. However, failure to send notice does not relieve the beneficiary of the obligation to refund the conditional payment as required by paragraph (a)(3)(i) of this section.

(b) *Determining the amount to be recovered from a beneficiary who received a liability insurance payment as a result of a judgment or settlement*—(1) *Basic rule.* The amount to be recovered from the beneficiary is the amount Medicare paid, less a proportionate share of the costs of procuring the judgment or settlement. If the Medicare payments equal or exceed the amount of the judgment or settlement, the total procurement costs are subtracted from the Medicare payments. The individual will not be required to refund more than the liability insurance payment minus the procurement costs.

(2) *Computation when Medicare payment is less than the amount of the judgment or settlement.* If the Medicare payment is less than the amount of the judgment or settlement—

(i) Determine the ratio of the Medicare payments to the total amount of the judgment or settlement;

(ii) Apply this ratio to the costs of procuring the judgment or settlement, including attorney fees; and

(iii) Subtract the Medicare share of procurement costs from the Medicare payments. The remainder is the amount of reimbursement to be refunded to the Medicare program.

(3) *Computation when Medicare payment equals or exceeds the amount of the judgment or settlement.* If the Medicare payment equals or exceeds the amount of the judgment or settlement, subtract the total procurement costs from the Medicare payment. The remainder, up to the amount of the li-

ability insurance payment after the procurement costs have been subtracted, is the amount of reimbursement to be refunded to the Medicare program.

[48 FR 14810, Apr. 5, 1983]

§ 405.325 Effect on benefit utilization and deductibles when services are payable under automobile medical, no-fault, or liability insurance.

(a) *Benefit utilization.* Inpatient services for which Medicare payment is not made (or if made is later recovered) because benefits are paid by an automobile medical or no-fault insurer or by a liability insurer will not be counted against the number of inpatient care days available to the beneficiary under Medicare Part A.

(b) *Deductibles.* Expenses for services for which Medicare payment is not made (or if made is later recovered) because benefits are paid by an automobile medical or no-fault insurer or by a liability insurer cannot be credited toward the Medicare Part A or Part B deductible amounts. If an individual is hospitalized twice in the same benefit period, and the first hospitalization is completely paid for by the insurer, the inpatient hospital deductible would apply to the second hospitalization.

[48 FR 14811, Apr. 5, 1983]

LIMITATIONS ON PAYMENT FOR SERVICES TO END-STAGE RENAL DISEASE BENEFICIARIES WHO ARE ALSO COVERED UNDER EMPLOYER GROUP HEALTH PLANS

§ 405.326 Scope and applicability.

(a) Sections 405.327 through 405.329 set forth policies and procedures for payment of benefits for services furnished to individuals who are entitled to Medicare solely on the basis of end-stage renal disease (ESRD) and who are also covered under an employer group health plan.

(b) In §§ 405.327 through 405.329 the following terms have the specified meanings:

(1) *"Employer"* means, in addition to individuals and organizations engaged in a trade or business, other entities exempt from income tax such as religious, charitable, and educational institutions, the governments of the United States, the individual States, the Territories, Puerto Rico, the Virgin Islands, Guam and the District of Columbia, and the agencies, instrumentalities, and political subdivisions of these governments.

(2) *"Employer group health plan"* or *"employer plan"* means any group health plan that—

(i) Is of, or contributed to by, an employer; and

(ii) Provides medical care directly or through other methods such as insurance or reimbursement, to current or former employees, or to current or former employees and their families.

(3) *"Secondary,"* when used to characterize Medicare payments, means that medicare benefits are payable only to the extent that payment cannot be made by one or more employer group health plans under which the Medicare beneficiary is covered.

[48 FR 14811, Apr. 5, 1983]

§ 405.327 Medicare benefits secondary to employer group health plan benefits.

(a) *General rules.* (1) Effective for months after September 1981, Medicare benefits are secondary to benefits payable under an employer plan, for services furnished to an ESRD beneficiary during a period of up to 12 consecutive months as specified in paragraphs (b) and (c) of this section.

(2) If the individual becomes entitled to Medicare after the 12-month period has begun, as set forth in paragraph (c) of this section, Medicare benefits are secondary only for that portion of the 12-month period that begins with the month of entitlement.

(3) During the period in which Medicare benefits are secondary, Medicare will—

(i) Pay primary benefits for Medicare covered services that are not covered by the employer plan; and

(ii) Make secondary payments, within the limits specified in § 405.328, to supplement the amount paid by the employer plan if that plan pays only a portion of the charge for the service.

(4) Any Medicare benefits payable within the 12-month period are secondary to employer policies or plans

even though the employer policy or plan states that its benefits are secondary to Medicare's or otherwise excludes or limits its payments to Medicare beneficiaries.

(b) *Beginning of 12-month period.* The period of 12 consecutive months specified by law begins with any month after September 1981 that is the earlier of the following months:

(1) The month in which the individual initiates a regular course of renal dialysis.

(2) In the case of an individual who receives a kidney transplant, the first month in which the individual could become entitled to Medicare if he or she filed a timely application, that is, the earliest of the following:

(i) The month in which the transplant is performed.

(ii) The month in which the individual is admitted to the hospital in preparation for, or anticipation of, a transplant that is performed within the next two months.

(iii) The second month before the month the transplant is performed, if performed more than 2 months after admission.

(c) *Beginning of period in which Medicare is secondary payer.* The period in which Medicare is secondary payer begins later than the beginning of the 12-month period (and therefore lasts less than 12 months) if the individual—

(1) Is subject to the 3-month waiting period for individuals who initiate renal dialysis but do not begin training for self-dialysis during the first 3 months of dialysis; or

(2) Files the application for Medicare entitlement more than 12 months after the month in which a 12-month period begins. (Under the Act, an application may not be retroactive for more than 12 months.)

(d) *Examples.* The following examples illustrate how to determine, in different situations, the number of months during which Medicare is secondary payer.

(1) *Individual filed a timely application and became entitled without a waiting period.* In October 1981, John began a regular course of dialysis and filed an application for Medicare. In December 1981, John began training for self-dialysis. Since John initiated self-dialysis training during the first 3 months of dialysis, he is exempt from the waiting period and becomes entitled as of October 1981, the first month of dialysis. In this situation, the month of entitlement coincides with the beginning of the 12-month period and Medicare is secondary payer during the entire period.

(2) *Individual filed a timely application and became entitled to Medicare after a waiting period.* (i) Janice started a regular course of renal dialysis in October 1981 and filed an application in the same month. The 12-month period begins with the October 1981, but the 3-month waiting period doesn't end until December 1981. The month of entitlement for Janice is January 1982. Medicare is secondary payer from January through September 1982.

(ii) Peter started a regular course of dialysis in January 1982, and was hospitalized and received a kidney transplant in March 1982. The 12-month period begins with January 1982. The kidney transplant cuts short the dialysis waiting period so that Peter becomes entitled in March 1982. Medicare is secondary payer from March through December 1982.

(3) *Individual did not file a timely application.* In January 1982, Katherine suffered kidney failure and received a kidney transplant but did not apply for Medicare until July, 1983. Since the application is retroactive for only 12 months, Katherine becomes entitled to Medicare in July 1982. The 12-month period begins in January 1982, the month in which Katherine could have been entitled if she had filed a timely application. Medicare is secondary payer from July through December 1982.

(e) *Effect of changed basis for Medicare entitlement.* If the basis for an individual's entitlement to Medicare changes from ESRD to age 65 or disability, the 12-month period terminates with the month before the month in which the change is effective.

(f) *Determinations for subsequent periods of ESRD entitlement.* If an individual has more than one period of entitlement based solely on ESRD, a period during which Medicare may be secondary payer will be determined for each period of entitlement, in accordance with this section.

[48 FR 14811, Apr. 5, 1983]

§ 405.328 Amounts of secondary medicare payment.

(a) *Services reimbursed on a reasonable charge basis.* The Medicare secondary payment will be the lowest of the following:

(1) The actual charge by the supplier, minus the amount paid by the employer plan.

(2) The amount that Medicare would pay if the services were not covered by the employer plan.

(3) The sum of the amounts that would have been paid by Medicare as primary payer and the employer plan as secondary payer, minus the amount actually paid by the employer plan.

(4) If the claim is filed under an assignment, the Medicare reasonable charge, minus the amount paid by the employer plan. (If the beneficiary does not assign the claim but files for direct payment, this limit does not apply.)

(b) *Services reimbursed on a reasonable cost basis.* The Medicare secondary payment will be the lower of the following:

(1) The lesser of the provider's reasonable cost or customary charges, minus any applicable deductible or coinsurance amount.

(2) The lesser of the provider's reasonable cost or customary charges, minus the amount paid by the employer plan.

(c) *Services reimbursed on a cost-related basis.* The Medicare secondary payment will be the lower of the following:

(1) The cost-related rate established for the service minus any applicable deductible or coinsurance amount.

(2) The cost-related rate established for the service, minus the amount paid by the employer plan.

(d) *Example of computation of Medicare secondary payment for services reimbursed on a reasonable charge basis.*

(1) Physician's charge for professional services	$120
(2) Employer plan's allowable charge	110
(3) Medicare reasonable charge	100
(4) As primary payer the employer plan pays 80 percent of allowable charge (.80 × 100)	88
(5) As primary payer, Medicare would pay 80 percent of reasonable charge (.80 × 100)	80
(6) As secondary payer, the employer plan would pay the difference between its allowable charge and the primary payment ($110 − $80)	30
(7) As secondary payer, Medicare pays the lowest of the amounts specified in paragraph (a) of this section:	
(i) The excess of the actual charge over the amount paid by the employer plan is $120 − $88	32
(ii) The amount Medicare would pay if the services were not covered by an employer plan is .80 × $100	80
(iii) The sum of the amounts that would have been paid by Medicare as primary payer and the employer plan as secondary payer, minus the amount actually paid by the employer plan is ($80 + $30 = $110) − $88	22
(iv) If the physician accepted assignment the Medicare reasonable charge minus the amount paid by the employer plan is $100 − $88	12

Since Medicare pays the lowest of the amounts determined under paragraph (a), the Medicare payment is $22 if the beneficiary filed for direct payment; $12 if the physician filed the claim under an assignment.

(e) *Effect of secondary payments on Part A utilization.* If Medicare pays secondary benefits, the beneficiary will be charged with utilization of Medicare benefits only to the extent that Medicare paid for the services.

(f) *Crediting expenses toward deductibles.* Expenses that would serve to meet the beneficiary's Part A or Part B deductible if Medicare were primary payer, will be credited to the deductible even if the expenses are reimbursed by the employer group health plan.

[48 FR 14812, Apr. 5, 1983]

§ 405.329 Conditional payments and recovery of payments.

If the Medicare intermediary or carrier knows from experience or ascertains that the employer plan's payments in general are substantially less prompt than Medicare's, it will pay conditional primary benefits. In that case—

(a) The claimant (beneficiary, provider, or supplier) must file a claim with the employer plan and, to the extent that the claimant receives payment, reimburse the amount that

Medicare paid in excess of its obligation as secondary payer;

(b) If payment is not received from the employer plan for any reason, HCFA may bring an action against the employer plan, and the beneficiary must cooperate in HCFA's action;

(c) HCFA may, as a prerequisite to making the conditional payment, require the beneficiary to authorize it to pursue the beneficiary's right against the employer plan if the beneficiary does not, and to promise to cooperate in HCFA's action;

(d) HCFA may waive recovery action if the probability of recovery or the amount involved does not warrant pursuit of the claim.

[48 FR 14812, Apr. 5, 1983]

PAYMENT FOR CERTAIN EXCLUDED SERVICES

§ 405.330 Payment for certain nonreimbursable expenses.

(a) Notwithstanding the exclusions set forth in § 405.310, payment may be made for services that involve custodial care (as specified in § 405.310(g)), or are not "reasonable and necessary" (as specified in § 405.310(k)), if—

(1) The items and services were furnished by a provider or supplier under assignment; and

(2) Neither the individual to whom the items and services were furnished, nor the provider or supplier who furnished the services knew, or could reasonably have been expected to know, that the items or services were excluded from coverage in accordance with § 405.310(g) or § 405.310(k).

(b) Payment may be made under this provision for not more than 2 days for inpatient hospital services, post-hospital SNF care, or home health services (as defined in §§ 409.10, 409,20, and 409.40, respectively) when the fiscal intermediary or PRO determines that additional time is required in order to arrange for post discharge care, and when the additional care is furnished after whichever of the following days is the earlier:

(1) The day on which the individual, to whom the services were furnished, has been determined, under § 405.334, to have knowledge, actual or imputed, that those services were excluded from coverage by reason of § 405.310(g) or § 405.310(k); or

(2) The day on which the provider of the services has been determined, under § 405.336, to have knowledge, actual or imputed, that the services were excluded from coverage as custodial care (§ 405.310(g)) or as not reasonable and necessary (§ 405.310(k)).

(Secs. 1102, 1871, 1879 of the Social Security Act; 42 U.S.C. 1302, 1395hh, 1395pp)

[40 FR 1024, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 56025, Dec. 15, 1983; 50 FR 15326, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985; 51 FR 6235, Feb. 21, 1986; 51 FR 9792, Mar. 21, 1986; 51 FR 41337, Nov. 14, 1986]

§ 405.332 Liability for certain noncovered items or services.

(a) Even though payment may not be made pursuant to § 405.330 only because the provisions of paragraph (a)(2) thereof are not met, the individual to whom the items or services were furnished will be indemnified by the program (in the case of items or services furnished after October 30, 1972), to the extent specified in paragraph (b) of this section, if:

(1) The individual paid the provider of services or other person, as the case may be, referred to in § 405.330(a)(1), all or some of the charges for such services; and

(2) Such individual did not know and could not have reasonably been expected to know that the expenses incurred for such items or services were excluded from coverage by reason of § 405.310(g) or § 405.310(k); and

(3) Such provider of services or other person, as the case may be, knew or could reasonably have been expected to know that the expenses incurred for such items or services were excluded from coverage; and

(4) Such individual files a proper request for such indemnification prior to the end of the sixth month following the month in which the payment specified in paragraph (a)(1) of this section was made or, if later, the month in which the intermediary or carrier informed the individual (or someone on his behalf) in writing that the individual would not be liable for items or services, except that for good cause

shown such 6-month period may be extended.

(b) The amount an individual may be indemnified pursuant to paragraph (a) of this section shall be the amount he paid as specified in paragraph (a)(1) of this section, less the amount for deductibles and coinsurance, had such items or services been covered under the program. Any payment thus made as indemnification is deemed to be an overpayment to the provider of services or other person, as the case may be, who received the payment referred to in paragraph (a)(1) of this section and shall be recoverable in accordance with the provisions of this part or other applicable provision of law.

[40 FR 1024, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 51 FR 6235, Feb. 21, 1986]

§ 405.334 Criteria for determining that a beneficiary has knowledge that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A beneficiary who receives noncovered services that constitute custodial care under § 405.310(g), or that are not reasonable and necessary under § 405.310(k), will be found to have known that these services were not covered if the criteria in paragraphs (b) and (c) of this section are met.

(b) *Written notice.* Written notice has been given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines. A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion. For example, program payment may not be made for the treatment of obesity, no matter what form the treatment may take. After the beneficiary who is treated for obesity with dietary control is informed in writing that Medicare will not pay for treatment of obesity, he or she will be presumed to know that there will be no Medicare payment for any form of subsequent treatment of this condition, including use of a combination of exercise, machine treatment, diet, and medication.

(c) *Source of notice.* The notice was given by one of the following:

(1) The PRO, intermediary, or carrier.

(2) The group or committee responsible for utilization review for the provider that furnished the services.

(3) The provider, practitioner, or supplier that furnished the service.

[51 FR 6235, Feb. 21, 1986]

§ 405.336 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A provider, practitioner, or supplier that furnished services that constitute custodial care under § 405.310(g), or that are not reasonable and necessary under § 405.310(k), will, under any one of the circumstances described in paragraphs (b) through (f) of this section, be found to have known that these services were not covered.

(b) *Notice from the PRO, intermediary or carrier.* The PRO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) *Notice from the utilization review committee or the beneficiary's attending physician.* The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) *Notice from a provider to the beneficiary.* The provider had informed the beneficiary that he or she no longer required covered services or that, before services were furnished, the services were not covered.

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of—

(1) Its receipt of HCFA notices, including manual issuances, bulletins or other written guides or directives from intermediaries, carriers or PROs, including notification of PRO screening

criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medicial procedures subject to preadmission review by the PRO; or

(2) Its knowledge of what are considered acceptable standards of practice by the local medical community.

[51 FR 6236, Feb. 21, 1986]

LIMITATIONS ON PAYMENT FOR SERVICES FURNISHED TO EMPLOYED AGED AND AGED SPOUSES OF EMPLOYED INDIVIDUALS

§ 405.340 General provisions.

(a) *Applicability.* The provisions of this section and of §§ 405.341 through 405.344 implement section 1862(b)(3) of the Social Security Act. They set forth policies and procedures for payment of benefits for services furnished to employed Medicare beneficiaries age 65 through 69, their spouses age 65 through 69, and the spouses age 65 through 69 of employed individuals through age 69 who are covered under employer group health plans of employers that employ 20 or more employees. These provisions are applicable to services furnished on or after January 1, 1983 except as specified in §§ 405.340(b)(3)(ii), 405.341(a)(3)(ii), and 405.341(d).

(b) *Definitions.* For purposes of this section, and §§405.341 through 405.344, the following definitions apply:

(1) "Employer group health plan" or "employer plan" means any group health plan that provides medical care, directly or through other methods such as insurance or reimbursement, to current or former employees, or to current or former employees and their families, and—

(i) Is of, or contributed to by, an employer of 20 or more employees; or

(ii) Is a multiemployer group health plan that has at least one employer with 20 or more employees. However, if such multiemployer plan can identify members who are employees of employers with less than 20 employees, those individuals and their spouses will be considered not to meet the conditions specified in § 405.341(a)(3).

(2) "Secondary", when used to characterize Medicare payments, means that Medicare benefits are payable to the extent that payment has not been made or cannot reasonably be expected to be made by one or more employer group health plans under which the Medicare beneficiary is covered.

(3) "Age 65 through 69" means a period beginning with the first day of the month in which an individual attains age 65 and ending with—

(i) For services furnished before July 18, 1984, the last day of the month in which the individual attains age 70, and

(ii) For services furnished on or after July 18, 1984, the last day of the month before the month in which the individual attains age 70.

An individual attains a particular age on the day preceding the anniversary of his or her birth.

(4) "Employer" means, in addition to individuals and organizations engaged in a trade or business, other entities exempt from income tax such as religious, charitable, and educational institutions, the governments of the United States, the individual States, the Territories, Puerto Rico, the Virgin Islands, Guam and the District of Columbia, and the agencies, instrumentalities and political subdivisions of these governments.

(c) *Referral of cases to Equal Employment Opportunity Commission (EEOC).* HCFA will refer cases of apparent noncompliance with the requirements of the Federal Age Discrimination in Employment Act (ADEA) to the EEOC.

[50 FR 41510, Oct. 11, 1985]

§ 405.341 Medicare benefits secondary to employer group health plans—General rules.

(a) Effective for services furnished in months after December 1982, Medicare benefits (Parts A and B) are secondary to benefits payable by an employer group health plan for any month in which an individual age 65 through 69—

(1) Is entitled to Part A of Medicare under § 406.10 of this chapter;

(2) Is not entitled (and could not upon filing an application become entitled) to Medicare on the basis of end-

stage renal disease as provided in § 406.13 of this chapter; and

(3) Is either—

(i) Employed and covered by reason of such employment by an employer group health plan that meets the definition in § 405.340(b)(1); or

(ii) An employed individual's spouse age 65 through 69 who by reason of that individual's employment is covered by an employer group health plan, and the employed individual is:

(A) With respect to services furnished before January 1, 1985, age 65 through 69; or

(B) With respect to services furnished after December 31, 1984, any age through 69.

The spouse may be entitled to Part A of Medicare on the basis of the employed individual's earnings record or the spouse's own earnings record.

(b) Medicare will pay primary benefits for Medicare covered services, if an individual is not covered under an employer group health plan for any reason, including refusal to accept the plan offered by the employer.

(c) Where the conditions specified in paragraph (a) of this section are met, Medicare will:

(1) Not pay primary benefits for otherwise covered services even though the employer plan states that its benefits are secondary to Medicare's or otherwise excludes or limits its payments to Medicare beneficiaries;

(2) Pay primary benefits for Medicare covered services that are not covered by the employer plan; and

(3) Make secondary payments under Parts A and B of Medicare within the limits specified in § 405.342 to supplement the primary benefits paid by the employer plan if that plan pays only a portion of the charge for the services.

(d) Beginning with services furnished on or after November 12, 1985, an individual who is receiving disability payments from an employer will not be considered employed for purposes of this section if—

(1) For the month before the month of attainment of age 65, the individual was entitled to disability benefits under Title II of the Social Security Act (20 CFR 404.315 and 404.350 of the Social Security Administration regulations); or

(2) The individual is not receiving remuneration subject to tax under the Federal Insurance Contributions Act (26 CFR 32.1 of the Internal Revenue Service regulations).

[48 FR 15906, Apr. 13, 1983, as amended at 50 FR 41511, Oct. 11, 1985; 50 FR 43703, Oct. 29, 1985; 51 FR 41351, Nov. 14, 1986]

§ 405.342 Amount of Medicare secondary payment.

(a) *Services reimbursed by Medicare on a reasonable charge basis.* The Medicare secondary payment will be the lowest of the following:

(1) The actual charge by the supplier minus the amount paid by the employer plan.

(2) The amount that Medicare would pay if the services were not covered by the employer plan.

(3) The higher of the Medicare reasonable charge or other amount which would be payable under Medicare (without regard to any applicable Medicare deductible or co-insurance amounts) or the employer plan's allowable charge (without regard to any deductible or co-insurance imposed by the plan) minus the amount actually paid by the employer plan.

(4) If the claim is filed under an assignment, the Medicare reasonable charge, minus the amount paid by the employer plan. (If the beneficiary does not assign the claim but files for direct payment, this limit does not apply.)

Example: An individual received treatment from a physician for which the physician charged $175. As primary payer, an employer plan allowed $150 of the charge and paid 80 percent of this amount or $120. The Medicare reasonable charge for this treatment is $125. The individual's Part B deductible had been met. As secondary payer, Medicare pays the lowest of the following amounts:

(a) Excess of actual charge minus the employer plan's payment: $175 − 120 = $55.

(b) Amount Medicare would pay if the services were not covered by employer plan: .80 × $125 = $100.

(c) Employer plan's allowable charge without regard to coinsurance imposed by the employer plan (since that amount is higher than the Medicare reasonable charge in this case) minus amount paid by employer plan: $150 − 120 = $30.

(d) If the physician accepted Medicare assignment, the Medicare reasonable charge minus the amount paid by employer plan: $125 – 120 = $5. (This limit does not apply if the claim is not assigned.)

(b) *Services reimbursed by Medicare on other than a reasonable charge basis.* The Medicare secondary payment will be the lesser of—

(1) The gross amount payable by Medicare (the amount payable by Medicare without considering the effect of the Medicare deductible and coinsurance or the payment by the employer group health plan) reduced by the applicable Medicare deductible and coinsurance; or

(2) The gross amount payable by Medicare reduced by the amount paid by the employer plan.

Example: (1) A hospital furnished 7 days of inpatient hospital care in 1984 to a Medicare beneficiary whose employer group health plan was primary payer. The provider's charges for Medicare covered services totalled $2200. The employer plan paid $1760. No part of the Medicare inpatient hospital deductible of $356 had been met.

If the gross amount payable by Medicare in this case is $2100, then as secondary payer, Medicare pays the lower of the following amounts:

(a) The gross amount payable by Medicare minus the Medicare inpatient hospital deductible: $2100 – 356 = $1744.

(b) The gross amount payable by Medicare minus the employer plan's payment: $2100 – 1760 = $340. The $356 deductible was satisfied by the employer plan so that the beneficiary incurred no out of pocket costs.

Thus, when Medicare is secondary, the hospital payment made by both the employer and Medicare on behalf of the employee is $2100. For this example, if the employee had rejected the employer plan, resulting in Medicare becoming the primary plan, the hospital payment made on behalf of the employee would be $1,744.

Example: (2) A hospital furnished 1 day of inpatient hospital care in 1984 to a Medicare beneficiary whose employer group health plan was primary payer. The provider's charges for Medicare covered services totalled $750. The employer plan paid $250. No part of the Medicare inpatient hospital deductible had been met previously, but the employer plan's payment is credited toward that deductible.

If the gross amount payable by Medicare in this case is $650, then as secondary payer, Medicare pays the lower of the following amounts:

(a) The gross amount payable by Medicare minus the Medicare deductible: $650 – 356 = $294.

(b) The gross amount payable by Medicare minus the employer plan's payment: $650 – 250 = $400.

The hospital may bill the beneficiary the $106. ($650 minus the $250 employer plan payment and minus the $294 Medicare payment = $106.)

This fully discharges the beneficiary's deductible obligation.

Thus, when Medicare is the secondary payer, the hospital payment made by both the employer plan and Medicare on behalf of the employee is $544. For this example, if the employee had rejected the employer plan, resulting in Medicare becoming the primary plan, the hospital payment made on behalf of the employee would be $294, and the employee would have paid $356 as a deductible.

(c) *Effect of secondary payments on Part A utilization.* If Medicare pays secondary benefits, the beneficiary will be charged with utilization of Medicare benefits only to the extent that Medicare paid for the services.

(d) *Crediting expenses toward deductibles.* Expenses that would serve to meet the beneficiary's Part A or Part B deductibles if Medicare were primary payer, will be credited to the deductibles even if the expenses are reimbursed by the employer group health plan.

[48 FR 15907, Apr. 13, 1983, as amended at 50 FR 41511, Oct. 11, 1985]

§ 405.343 Limitation on right of provider to charge a beneficiary.

A provider of services or any other facility which is reimbursed on other than a reasonable charge basis may not charge a beneficiary or any other party for Medicare covered services if the provider or facility has been paid by an employer plan an amount that equals or exceeds any applicable Medicare deductible and coinsurance amounts and any charge made under § 413.35 of this chapter.

[50 FR 41512, Oct. 11, 1985, as amended at 51 FR 34792, Sept. 30, 1986]

§ 405.344 Conditional payment and recovery of payments.

(a) If the conditions specified in § 405.341(a) are met, conditional Medicare payment may be made when the claimant (beneficiary, provider, or supplier) has filed a claim under the employer plan, but the claim is denied in whole or in part by the employer plan for any reason.

(b) If a conditional Medicare payment is made, the following rules apply:

(1) The claimant must reimburse Medicare up to the amount it paid if the claimant subsequently receives payment from the employer plan.

(2) If, for any reason, primary payment is not received from the plan, HCFA may—

(i) Bring an action against the employer or the plan as appropriate, and the beneficiary must cooperate in HCFA's action; and

(ii) Refer the case to the EEOC in accordance with § 405.340(c).

(c) HCFA may, as a prerequisite for the conditional payment, require the beneficiary to authorize it to pursue the beneficiary's rights against the employer or the plan if the beneficiary does not, and to promise to cooperate in HCFA's action.

(d) HCFA may waive recovery action if the probability of recovery or the amount involved does not warrant pursuit of the claim.

(e) Any primary Medicare payment made for services furnished on or after January 1, 1983, to an individual who meets the conditions in § 405.341(a) is a conditional payment for purposes of paragraphs (b)(1) and (b)(2) of this section.

[48 FR 15907, Apr. 13, 1983, as amended at 50 FR 41512, Oct. 11, 1985]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under Title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.356, where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or (2) the provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Health Care Financing Administration that more than the correct amount was paid was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid.

[41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.351 Incorrect payments for which the individual is not liable.

Where an incorrect payment has been made to a provider of services or other person, the individual is liable only to the extent that he has benefited from such payment.

§ 405.352 Adjustment of Title XVIII incorrect payments.

Where an individual is liable for an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) adjustment is made (to the extent of such liability) by:

(a) Decreasing any payment under Title II of the Act, or under the Railroad Retirement Act of 1937, to which the individual is entitled; or

(b) In the event of the individual's death before adjustment is completed, by decreasing any payment under Title II of the Act, or under the Railroad Retirement Act of 1937 payable to the estate of the individual or to any other person, that are based on the individual's earnings record (or compensation).

[31 FR 13534, Oct. 20, 1966, as amended by 41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.353 Certification of amount that will be adjusted against individual Title II or railroad retirement benefits.

As soon as practicable after any adjustment is determined to be necessary, the Secretary, for purposes of this subpart, shall certify the amount of the overpayment or payment (see § 405.350) with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1937, such certification shall be made to the Railroad Retirement Board.

§ 405.354 Procedures for adjustment or recovery—Title II beneficiary.

The procedures applied in making an adjustment or recovery in the case of a Title II beneficiary are the applicable procedures of 20 CFR 404.502.

[31 FR 13534, Oct. 20, 1966, as amended at 32 FR 18027, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.355 Waiver of adjustment or recovery.

(a) The provisions of § 405.352 may not be applied and there may be no adjustment or recovery of an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) in any case where such incorrect payment has been made with respect to an individual who is without fault, or where such adjustment or recovery would be made by decreasing payments to which another person who is without fault is entitled as provided in section 1870(b) of the Act where such adjustment or recovery would defeat the purpose of Title II or Title XVIII of the Act or would be against equity and good conscience. (See 20 CFR 404.509 and 404.512.)

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault shall be deemed to be against equity and good conscience if the determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual. (See §§ 405.330-405.332 for conditions under which payment may be made for items or services furnished after October 30, 1972 which are noncovered by reasons of § 405.310 (g) and (k).)

[41 FR 1493, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.356 Principles applied in waiver of adjustment or recovery.

The principles applied in determining waiver of adjustment or recovery (§ 405.355) are the applicable principles of 20 CFR 404.506-404.509, 404.510a, and 404.512.

[35 FR 6321, Apr. 18, 1970. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.359 Liability of certifying or disbursing officer.

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person:

(a) Where the adjustment or recovery of such amount is waived (see § 405.355), or

(b) Where adjustment (see § 405.352) or recovery is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

SUSPENSION OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

§ 405.370 Suspension of Medicare payments to providers and suppliers.

(a) Medicare payments to providers and suppliers, as authorized under this chapter (excluding payments to beneficiaries), may be suspended, in whole or in part, by an intermediary or a carrier when—

(1) The intermediary or carrier has determined that the provider or other supplier to whom such payments are to be made has been overpaid under title XVIII of the Social Security Act, or

(2) The intermediary or carrier has reliable evidence, although additional evidence may be needed for a determi-

nation, that such overpayment exists or that the payments to be made may not be correct.

(b) A suspension shall be put into effect only after the provisions in §§ 405.371 and 405.372 have been complied with and the intermediary or carrier has determined that the suspension of payments, in whole or in part, is needed to protect the program against financial loss. The provisions of this section and §§ 405.371–405.373 shall be effective on May 27, 1972.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6647, Mar. 2, 1988]

§ 405.371 Proceeding for suspension.

(a) *General.* Whenever the intermediary or carrier has determined that a suspension of payments under § 405.370 should be put into effect with respect to a provider of services or other supplier of services, the intermediary or carrier shall notify the provider or other supplier of its intention to suspend payments, in whole or in part, and the reasons for making such suspension. The provider or other supplier will be given the opportunity to submit any statement (including any pertinent evidence) as to why the suspension shall not be put into effect and shall have 15 days following the date of notification to submit such statement, unless the intermediary or carrier for good cause imposes a shorter period. The intermediary or carrier may, for good cause shown, extend the time within which the statement may be submitted. If no statement is received within the 15-day period or such other period as specified in the notice, the suspension shall go into effect.

(b) *Fraud or misrepresentation.* The provisions of paragraph (a) of this section shall not apply where the intermediary or carrier has reliable evidence that the circumstances giving rise to the need for a suspension of payments involves fraud or willful misrepresentation. Instead, the intermediary or carrier may suspend payments without first notifying the provider or other supplier of an intention to suspend payments. The provider or other supplier will be notified of such suspension and the reasons for taking such action.

(c) *Notice of amount of program reimbursement.* The provisions of paragraph (a) of this section shall not apply where the intermediary, after furnishing a provider a written notice of the amount of program reimbursement pursuant to § 405.1803, suspends payment under paragraph (b) of such § 405.1803.

(d) *Failure to furnish information requested.* The provisions of paragraph (a) of this section shall not apply where the intermediary or carrier suspends payments to a provider or other supplier of services because such provider or supplier of services has failed to submit evidence requested by such intermediary or carrier which is needed to determine the amounts due such provider or supplier under the program (sections 1815 and 1833(e) of the Act).

[37 FR 10723, May 27, 1972, as amended at 41 FR 52050, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.372 Submission of evidence and notification of administrative determination to suspend.

When pursuant to § 405.371(a) the provider or other supplier submits a statement, the intermediary or carrier shall consider such statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and make a determination as to whether the facts justify a suspension authorized by § 405.373. If the intermediary or carrier determines that a suspension should go into effect, written notice of such determination will be sent to the provider or other supplier. Such notice will contain specific findings on the conditions upon which the suspension was based, and an explanatory statement for the final decision.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.373 Subsequent action by intermediary or carrier.

(a) Where a suspension is put into effect by reason of § 405.370(a)(1), such suspension shall remain in effect until whichever of the following first occurs:

(1) The overpayment is liquidated, (2) the intermediary or carrier enters into an agreement with the provider or other supplier for liquidation of the overpayment, or (3) the intermediary or carrier, on the basis of subsequently acquired evidence or otherwise, determines that there is no overpayment; except that the intermediary or carrier may at any time adjust such suspension for an appropriate period if it determines that continuation of the suspension would cause irreparable harm to the provider or other supplier.

(b) Where the suspension is put into effect by reason of § 405.370(a)(2), the intermediary or carrier will take timely action after such suspension to obtain such additional evidence it may need to make a determination as to whether an overpayment exists or the payments may be made (i.e., evidence from the records of the provider or other supplier of services). All reasonable efforts will be made by the intermediary or carrier to expedite such determinations. As soon as such determination is made, the provider or other supplier will be informed and, where appropriate such suspension will be rescinded or adjusted to take into account such determination. If such suspension is not rescinded, it shall remain in effect as specified in paragraph (a) of this section.

(c) The provisions of this section shall not apply where the intermediary or carrier, in suspending payments pursuant to § 405.370, has reliable evidence that the circumstances giving rise to such suspension involve fraud or serious misrepresentation.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.374 Collection and compromise of claims for overpayments.

(a) *Scope.* This section contains requirements and procedures for the compromise of, or suspension or termination of collection action on, claims for overpayments against a provider, physician, or other supplier of services under the Medicare program. It is adopted pursuant to the Federal Claims Collection Act (31 U.S.C. 951-953). Collection and compromise of claims against Medicare beneficiaries is explained at 20 CFR 404.515.

(b) *Definitions.* As used in this section, *"debtor"* means a provider of services or a physician or other supplier of services that has been overpaid under title XVIII of the Social Security Act. It includes an individual, partnership, corporation, estate, trust, or other legal entity.

(c) *Basic conditions.* A claim for recovery of Medicare overpayments against a debtor may be compromised, or collection action on it may be suspended or terminated, by the Health Care Financing Administration (HCFA) if:

(1) The claim does not exceed $20,000, exclusive of interest; and

(2) There is no indication of fraud, the filing of a false claim, or misrepresentation on the part of the debtor or any director, partner, manager, or other party having an interest in the claim.

(d) *Basis for compromise.* A claim may be compromised for one or more of the following reasons:

(1) The debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount within a reasonable time;

(2) The debtor refuses to pay the claim in full and the United States is unable to collect the full amount within a reasonable time by legal proceedings;

(3) There is real doubt the United States can prove its case in court; or

(4) The cost of collecting the claim does not justify enforced collection of the full amount.

(e) *Basis for termination.* Collection action may be terminated for one or more of the following reasons:

(1) The United States cannot enforce collection of any significant sum;

(2) The debtor cannot be located, there is no security to be liquidated, the statute of limitations has run, and the prospects of collecting by offset are too remote to justify retention of the claim;

(3) The cost of further collection action is likely to exceed any recovery;

(4) It is determined the claim is without merit; or

(5) Evidence to substantiate the claim is no longer available.

(f) *Basis for suspension.* Collection action may be suspended for either of the following reasons if future collection action is justified based on potential productivity, including foreseeable ability to pay, and size of claim:

(1) The debtor cannot be located; or

(2) The debtor is unable to make payments on the claim or to fulfill an acceptable compromise.

(g) *Factors considered.* In determining whether a claim will be compromised, or collection action terminated or suspended, HCFA will consider the following factors:

(1) Age and health of the debtor, present and potential income, inheritance prospects, possible concealment or fraudulent transfer of assets, and the availability of assets which may be reached by enforced collection proceedings, for compromise under paragraph (d)(1) of this section, termination under paragraph (e)(1) of this section, and suspension under paragraph (f)(2) of this section;

(2) Applicable exemptions available to a debtor and uncertainty concerning the price of the property in a forced sale, for compromise under paragraph (d)(2) of this section and termination under paragraph (e)(1) of this section; and

(3) The probability of proving the claim in court, the probability of full or partial recovery, the availability of necessary evidence, and related pragmatic considerations, for compromise under paragraph (d)(3) of this section.

(h) *Amount of compromise.* The amount accepted in compromise will be reasonable in relation to the amount that can be recovered by enforced collection proceedings.

Consideration shall be given to the following:

(1) The exemptions available to the debtor under State or Federal law;

(2) The time necessary to collect the overpayment;

(3) The litigative probabilities involved; and

(4) The administrative and litigative costs of collection where the cost of collecting the claim is a basis for compromise.

(i) *Payment of compromise*—(1) *Time and manner.* Payment of the amount that HCFA has agreed to accept as a compromise in full settlement of a Medicare overpayment claim must be made within the time and in the manner prescribed by HCFA. An overpayment claim is not compromised or settled until the full payment of the compromised amount has been made within the time and in the manner prescribed by HCFA.

(2) *Failure to pay compromised amount.* Failure of the debtor or the estate to make payment as provided by the comprise reinstates the full amount of the overpayment claim, less any amounts paid prior to the default.

(j) *Effect of compromise, or suspension, or termination of collection action.* Any action taken by HCFA under this section regarding the compromise of an overpayment claim, or termination or suspension of collection action on an overpayment claim, is not an initial determination for purposes of the appeal procedures under Subparts G, H, and R of this part.

[43 FR 59381, Dec. 20, 1978]

§ 405.375 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* This section implements section 1885 of the Act, which provides for withholding Medicare payments to certain Medicaid providers specified in paragraph (b) of this section that have not arranged to repay Medicaid overpayments as determined by the Medicaid agency or have failed to provide information necessary to determine the amount of overpayment.

(b) *When withholding may be used.* HCFA may withhold Medicare payments to recover Medicaid overpayments that a Medicaid agency has been unable to collect, if—

(1) The Medicaid agency has followed the procedure specified in § 447.31 of this chapter, and

(2) The institution or person is one described in paragraphs (c)(1) or (c)(2) of this section.

(c) *Institutions or persons affected*—(1) HCFA may withhold Medicare payments to recover Medicaid overpayments with respect to any of the following entities that has or had in effect, an agreement with a Medicaid agency to furnish services under an approved Medicaid State plan:

(i) An institutional provider that has in effect an agreement under section 1866 of the Act.

(ii) A physician or supplier who has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act.

(2) HCFA may withhold Medicare payment from an institution or person specified in paragraph (c)(1) of this section that—

(i) Has not made arrangements satisfactory to the Medicaid agency to repay; or

(ii) Has not provided information to the Medicaid agency necessary to enable the agency to determine the existence or amount of Medicaid overpayment.

(d) *Amount to be withheld*—(1) HCFA will contact the appropriate intermediary or carrier to determine the amount of Medicare payment to which the institution or person is entitled.

(2) HCFA may require the intermediary or carrier to withhold Medicare payments to the institution or person by the lesser of the following amounts;

(i) The amount of the Medicare payments to which the institution or person would otherwise be entitled.

(ii) The total Medicaid overpayment to the institution or person.

(e) *Notice of withholding*—If HCFA intends to withhold payments under this section, HCFA will notify by certified mail, return receipt requested, the institution or person and the intermediary or carrier responsible for making Medicare payment to the institution or person of the intention to withhold Medicare payments. The notice will include:

(1) Identification of the institution or person; and

(2) The amount of Medicaid overpayment to be withheld from payments to which the institution or person would otherwise be entitled under Medicare.

(f) *Termination of withholding.* HCFA will terminate the withholding if—

(1) The Medicaid overpayment is completely recovered;

(2) The institution or person makes an agreement satisfactory to the Medicaid agency to repay the overpayment; or

(3) The Medicaid agency determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(g) *Disposition of funds withheld.* HCFA will return to the Medicaid agency amounts withheld under this section to offset the agency's Medicaid overpayment.

[50 FR 19688, May 10, 1985]

§ 405.376 Interest charges on overpayments and underpayments to providers and suppliers.

(a) *Basis and purpose.* This section, which implements sections 1815(d) and 1833(j) of the Social Security Act, and authority granted under the Federal Claims Collection Act, provides for the charging and payment of interest on overpayments and underpayments to Medicare providers, suppliers, and physicians and other practitioners.

(b) *Basic rules.* (1) HCFA will charge interest on overpayments, and pay interest on underpayments, to providers and suppliers of services (including physicians and other practitioners), except as specified in paragraphs (f) and (h) of this section.

(2) Interest will accrue from the date of the final determination as defined in paragraph (c) of this section, and will either be charged on the overpayment balance or paid on the underpayment balance for each 30-day period that payment is delayed. (Periods of less than 30 days will be treated as a full 30-day period, and the 30-day interest charge will be applied to any balance.)

(c) *Definition of final determination.* (1) For purposes of this section, a final determination is deemed to occur—

(i) Upon the issuance of both a Notice of Program Reimbursement (NPR), as discussed in § 405.1803, and either (A) a written demand for payment, or (B) a written determination of an underpayment by the intermediary after the cost report is filed;

(ii) When an NPR is not utilized as a notice of determination (primarily under Part B), upon the issuance of either (A) a written determination that an overpayment exists and a written demand for payment, or (B) a written determination of an underpayment. (Examples of when an NPR is not utilized are carrier reasonable charge determinations under 42 CFR 405.501 and initial retroactive adjustment determinations under 42 CFR 413.64(f)(2) of this chapter. In the latter case, a final determination is deemed to have been made if the provider does not dispute the adjustment determination within 15 days of the notice of the determination. If the provider does dispute portions of the determination, a final determination is deemed to have been made on those portions when the intermediary issues a new determination in response to the dispute);

(iii) Upon the due date of a timely-filed cost report that (A) indicates an amount is due HCFA, and (B) is not accompanied by payment in full. (If an additional overpayment or underpayment is determined by the carrier or intermediary, a final determination on the additional amount will be made in accordance with paragraphs (c)(1)(i) or (c)(1)(ii) of this section); or,

(iv) With respect to a cost report that is not filed on time, the day following the date the cost report was due (plus a single extension of time not to exceed 30 days if granted for good cause), until such time as a cost report is filed. (When such cost report is subsequently filed, there will be an additional determination as specified in paragraphs (c)(1) (i), (ii) or (iii) of this section.)

(2) Except as required by any subsequent administrative or judicial reversal, interest will accrue from the date of final determination as specified in this subsection.

(d) *Rate of interest.* (1) The interest rate on overpayments and underpayments will be the prevailing rate(s) specified in bulletins issued under § 8020.20 of the Treasury Fiscal Requirements Manual.

(2) If a provider or a supplier of services signs a repayment agreement with HCFA for the overpayment—

(i) The rate of interest specified in the agreement will continue unchanged if there is no default;

(ii) Interest on the balance of the debt may be changed to the prevailing rate if—

(A) The provider or supplier of services defaults on an installment; and

(B) The prevailing rate in effect on the date the installment becomes overdue is higher than the rate specified in the agreement.

(e) *Accrual of interest.* (1) If a cost report is filed that does not indicate an amount is due HCFA but the intermediary makes a final determination that an overpayment exists, or if a carrier makes a final determination that an overpayment to a physician or supplier exists, interest will accrue beginning with the date of such final determination. Interest will continue to accrue during periods of administrative and judicial appeal and until final disposition of the claim.

(2)(i) If a cost report is filed and indicates that an amount is due HCFA, interest on the amount due will accrue from the due date of the cost report unless—

(A) Full payment on the amount due accompanies the cost report; or

(B) The provider and the intermediary agree in advance to liquidate the overpayment through a reduction in interim payments over the next 30-day period.

(ii) If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination.

(iii) The interest rate on each of the final determinations of an overpayment will be the rate of interest in effect on the date the determination is made.

(3) In the case of a cost report that is not filed on time, interest also will accrue on a determined overpayment from the day following the due date of the report (plus a single extension of time not to exceed 30 days if granted for good cause, as specified in § 413.24(f)) of this chapter, to the time the cost report is filed.

(4) If an intermediary or a carrier makes a final determination that an underpayment exists, interest to the

provider or the supplier will accrue from the date of notification of the underpayment.

(f) *Waiver of interest charges.* (1) When an intermediary or a carrier makes a final determination that an overpayment or underpayment exists, as specified in paragraphs (e)(1), (e)(2)(ii), and (e)(4)—

(i) Interest charges will be waived if the overpayment or underpayment is completely liquidated within 30 days from the date of the final determination.

(ii) HCFA may waive interest charges if it determines that the administrative cost of collecting them exceeds the interest charges.

(2) Interest will not be waived for that period of time during which the cost report was due but remained unfiled for more than 30 days, as specified in paragraph (e)(3) of this section.

(g) *Rules applicable to partial payments.* If an overpayment is repaid in installments or recouped by withholding from several payments due the provider or supplier of services—

(1) Each payment or recoupment will be applied first to accrued interest and then to the principal; and

(2) After each payment or recoupment, interest will accrue on the remaining unpaid balance.

(h) *Exceptions to applicability.* (1) The provisions of this section do not apply to the time period for which interest is payable under § 405.64(j) of this chapter because the provider seeks judicial review of a decision of the Provider Reimbursement Review Board, or a subsequent reversal, affirmance, or modification of that decision by the Administrator. Prior to that time, until the provider seeks judicial review, interest will accrue at the rate specified in this section.

(2) If an overpayment or an underpayment determination is reversed administratively or judicially, and the reversal is no longer subject to appeal, appropriate adjustments will be made with respect to the overpayment or underpayment and the amount of interest charged.

(i) *Non-allowable cost.* As specified in § 413.153 of this chapter, interest accrued on overpayments and interest on funds borrowed specifically to repay overpayments are not considered allowable costs, up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (e.g., capital improvements).

(See § 405.153(a)(2) of this chapter for exceptions based on administrative or judicial reversal.)

[47 FR 54814, Dec. 6, 1982, as amended at 49 FR 36102, Sept. 14, 1984; 49 FR 44472, Nov. 7, 1984; 51 FR 34792, Sept. 30, 1986]

Subpart D—Principles of Reimbursement for Services by Hospital-Based Physicians

AUTHORITY: Secs. 1102, 1871, and 1887 of the Social Security Act as amended (42 U.S.C. 1302, 1395hh, and 1395xx).

PAYMENTS TO TEACHING HOSPITALS

§ 405.465 Determining reimbursement for certain physician and medical school faculty services rendered in teaching hospitals.

(a) *General.* Payments for services of physicians in teaching hospitals rendered to patients will be made by the health insurance program on the basis of reasonable cost where the hospital exercises the election as provided for in § 405.521 of this part. Where such election is made:

(1) Direct medical and surgical services to health insurance program patients, including supervision of interns and residents, rendered in a teaching hospital by physicians on the hospital staff are reimbursable as provider services on a reasonable-cost basis, as provided for in paragraph (b) of this section.

(2) Reimbursement for certain medical school costs may be made as provided for in paragraph (c) of this section.

(3) Payments for services donated by volunteer physicians to health insurance program patients will be made to a fund designated by the organized medical staff of the teaching hospital or medical school as provided for in paragraph (d) of this section.

(b) *Reasonable cost of direct medical and surgical services (including supervision of interns and residents) ren-*

dered in a teaching hospital by physicians on the hospital staff. Direct medical and surgical services to patients, including supervision of interns and residents, rendered in a teaching hospital by physicians on the hospital staff are reimbursable as provider services on a reasonable-cost basis. For purposes of this paragraph, reasonable cost is defined as the direct salary paid to such physicians, plus applicable fringe benefits. Such costs must be allocated to such services as provided by paragraph (j) of this section and apportioned to program beneficiaries as provided by paragraph (g) of this section. Other allowable costs incurred by the provider related to the services described in this paragraph are reimbursable subject to the requirements applicable to all other provider services.

(c) *Reasonable costs incurred by a teaching hospital for the services rendered by a medical school or related organization in a hospital.* An amount not in excess of the reasonable cost (as defined in paragraphs (c) (1) and (2) of this section) incurred by a teaching hospital for services rendered by a medical school or organization related thereto within the meaning of § 413.17 for certain costs to the medical school (or such related organization) in rendering services in the hospital are reimbursable to the hospital by the health insurance program provided that such costs would be reimbursable if incurred directly by the hospital rather than under such arrangement.

(1) *Reasonable costs of direct medical and surgical services (including supervision of interns and residents in the care of individual patients) rendered in a teaching hospital by physicians on the faculty of a medical school or organization related to the medical school.* (i) In situations where the medical school (or organization related to the medical school) and the hospital are related by common ownership or control in accordance with § 413.17, the cost of such services are allowable costs to the hospital under the provisions of § 413.17 and the reimbursable costs to the hospital are determined under the provisions of this section in the same manner as the costs incurred for physicians on the hospital staff and without regard to payments made to the medical school by the hospital.

(ii) Where the medical school and the hospital are not related organizations under the provisions of § 413.17 and the hospital makes payment to the medical school for the costs of such services rendered to all patients, reimbursement will be made by the health insurance program to the hospital for the reasonable cost incurred by the hospital for its payments to the medical school for services to health insurance beneficiaries. Costs incurred under such an arrangement must be allocated to the full range of services provided to the hospital by the medical school physicians on the same basis as provided for under paragraph (j) of this section and costs so allocated to direct medical and surgical services to hospital patients must be apportioned to health insurance beneficiaries as provided for under paragraph (g) of this section. Where the medical school and the hospital are not related organizations under the provisions of § 413.17 and the hospital makes payment to the medical school only for the costs of such services rendered to health insurance program patients, costs of the medical school not to exceed 105 percent of the sum of physicians' direct salaries, applicable fringe benefits, employer's portion of FICA taxes, federal and state unemployment taxes, and workmen's compensation paid by the medical school or an organization related thereto may be recognized as allowable cost of the medical school. Such allowable medical school costs must be allocated to the full range of services rendered by the physicians of the medical school or organization related thereto as provided by paragraph (j) of this section. Costs so allocated to direct medical and surgical services to hospital patients must be apportioned to health insurance program beneficiaries as provided by paragraph (g) of this section.

(2) *Reasonable costs of other than direct medical and surgical services rendered in a teaching hospital by medical school faculty (or organization related to the medical school).* Such costs are determined in accord-

ance with paragraph (c)(1) of this section except that:

(i) Where the hospital makes payment to the medical school for other than direct medical and surgical services rendered to all patients, such payments are subject to the required cost-finding and apportionment methods applicable to the cost of other hospital services (excepting direct medical and surgical services rendered to patients), or (ii) where the hospital makes payment to the medical school only for such services rendered to health insurance program patients, then the cost of services which are so reimbursed are not subject to cost-finding and apportionment as otherwise provided by this subpart and the reasonable cost reimbursed by the health insurance program must be determined on the basis of the health insurance ratio(s) used in the apportionment of all other provider costs (excepting physicians' direct medical and surgical services rendered to patients) applied to the allowable medical school costs incurred by the medical school for the services rendered to all patients of the hospital.

(d) *"Salary Equivalent" payments for physicians' direct medical and surgical services rendered to health insurance program patients in a teaching hospital by physicians on the voluntary staff of the hospital (or medical school or organization related thereto under arrangement with the hospital).*

(1) Payments will be made to a fund as defined in § 405.466 for direct medical and surgical services rendered on a regularly scheduled basis by physicians on the unpaid voluntary medical staff of the hospital (or medical school under arrangement with the hospital) to health insurance program patients. Such payments represent compensation for contributed medical staff time which, if not contributed, would have to be obtained through employed staff on a reimbursable basis. Payments for volunteer services are determined by applying to the regularly scheduled contributed time an hourly rate not to exceed the equivalent of the average direct salary (exclusive of fringe benefits) paid to all full-time, salaried physicians (other than interns and residents) on the hospital staff or, where the number of full-time salaried physicians is minimal in absolute terms or in relation to the number of physicians on the voluntary staff, to physicians at like institutions in the area. This "salary equivalent" is a single hourly rate covering all physicians regardless of specialty, and is applied to the actual regularly scheduled time contributed by the physicians in rendering direct medical and surgical services to health insurance program patients including supervision of interns and residents in such care. A physician who receives any compensation from the hospital or a medical school related to the hospital by common ownership or control (within the meaning of § 413.17), for direct medical and surgical services rendered to any patient in the hospital will not be considered an unpaid voluntary physician for purposes of this paragraph. Where, however, a physician receives compensation from the hospital or related medical school or organization related thereto for only services which are other than direct medical and surgical services, a salary equivalent payment for his regularly scheduled direct medical and surgical services to health insurance program patients of the hospital may be imputed. However, the sum of the imputed value for volunteer services and his actual compensation from the hospital and the related medical school (or organization related thereto) may not exceed the amount that would have been imputed if all of his hospital and medical school services (compensated and volunteer) had been (i) volunteer services, or (ii) at the rate of $30,000 per year, whichever is less.

(2) The following examples illustrate how the allowable imputed value for volunteer services is determined. In each example, it has been assumed that the average salary equivalent hourly rate is equal to the hourly rate for the individual physician's compensated services.

Example No. 1. Dr. Jones received $3,000 a year from Hospital X for services other than direct medical services to all patients, e.g., utilization review, administrative services, etc. Dr. Jones also voluntarily rendered direct medical services to health insurance program patients. The imputed value of the volunteer services amounted to $10,000 for the cost-reporting period. The full imputed value of Dr. Jones' volunteer direct medical services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($3,000) does not exceed $30,000.

Example No. 2. Dr. Smith received $25,000 from Hospital X for services as a department head in a teaching hospital. Dr. Smith also voluntarily rendered direct medical services to health insurance program patients. The imputed value of the volunteer services amounted to $10,000. Only $5,000 of the imputed value of volunteer services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($25,000) exceeds the $30,000 maximum amount allowable for all his services.

Computation:

Maximum amount allowable for all services performed by Dr. Smith for purposes of this computation	$30,000
Less compensation received from hospital X for other than direct medical services to individual patients	$25,000
Allowable amount of imputed value for the volunteer services rendered by Dr. Smith	$5,000

Example No. 3. Dr. Brown is not compensated by Hospital X for any services rendered in the hospital. Dr. Brown voluntarily rendered direct surgical services to health insurance program patients for a period of 6 months and the imputed value of these services amounted to $20,000. The allowable amount of the imputed value for volunteer services rendered by Dr. Brown would be limited to $15,000 ($30,000 × 6/12).

(3) The amount of the imputed value for volunteer services applicable to health insurance program beneficiaries and payable to a fund will be determined in accordance with the Aggregate Per Diem Method described in paragraph (g) of this section.

(4) Health insurance payments to a fund will be used by the fund solely for improvement of care of hospital patients or for educational or charitable purposes (which may include but are not limited to medical and other scientific research). No personal financial gain, either direct or indirect, from benefits of the fund may inure to any of the hospital staff physicians, medical school faculty, or physicians for whom the health insurance program imputes costs for purposes of payment into the fund. Expenses met from contributions made to the hospital from such a fund will not be included as a reimbursable cost when expended by the hospital, and depreciation expense will not be allowed with respect to equipment or facilities donated to the hospital by such a fund or purchased by the hospital from monies in such a fund.

(e) *Requirements for reimbursement for physicians' direct medical and surgical services (including supervision of interns and residents) in the care of individual patients rendered in a teaching hospital*—

(1) *Physicians on the hospital staff.* The requirements under which the costs of physicians' direct medical and surgical services (including supervision of interns and residents) in the care of individual patients rendered to health insurance program patients will be allowed are the same as those applicable to the cost of all other covered provider services except that the costs of these services are separately determined as provided by this section and are not subject to cost-finding as described in § 413.24 of this chapter.

(2) *Physicians on the medical school faculty.* Reimbursement will be made to a hospital by the health insurance program for the costs of services of physicians on the medical school faculty, provided that in situations where the medical school is not related to the hospital (within the meaning of § 413.17), the hospital does not make payment to the medical school for services rendered to all patients and the following requirements are met: (In situations where the hospital makes payment to the medical school for services rendered to all patients, these requirements do not apply (see § 405.465(c)(1)(ii)).

(i) There is a written agreement between the hospital and the medical school or organization related thereto, specifying the types and extent of services to be furnished by the medical school and specifying that the hospital must pay to the medical school an amount at least equal to the reasonable cost (as defined in paragraph (c) of this section) of providing such services to health insurance program patients.

(ii) Such costs are paid to the medical school by the hospital no later than the date on which the cost report covering the period in which the services were rendered is due, and

(iii) Payment for such services furnished under such an arrangement would be made by the health insurance program to the hospital had such services been furnished directly by the hospital.

(3) *Physicians on the voluntary staff of the hospital (or medical school under arrangement with the hospital).* Payments will be made by the health insurance program on a "salary equivalent" basis (as defined in paragraph (d) of this section) to a fund where the conditions outlined in § 405.466 are met.

(f) *Requirements for reimbursement for medical school faculty services other than physicians' direct medical and surgical services rendered in a teaching hospital.* Reimbursement will be made to a hospital by the health insurance program for the costs of medical school faculty services other than physicians' direct medical and surgical services rendered in a teaching hospital where the requirements described in paragraph (e) of this section are met.

(g) *Aggregate per diem methods of apportionment for physicians' direct medical and surgical services (including supervision of interns and residents) in the care of individual patients, rendered in a teaching hospital—*

(1) *Aggregate per diem method of apportionment for the costs of physicians' direct medical and surgical services (including supervision of interns and residents) in the care of individual patients.* The cost of physicians' direct medical and surgical services rendered in a teaching hospital to health insurance program beneficiaries is determined on the basis of an average cost per diem as defined in paragraph (h)(1) of this section for physicians' direct medical and surgical services to all patients (see § 405.521) for each of the following categories of physicians:

(i) Physicians on the hospital staff.

(ii) Physicians on the medical school faculty.

(2) *Aggregate per diem method of apportionment for the imputed value of physicians' volunteer direct medical and surgical services.* The imputed value of physicians' direct medical and surgical services rendered to health insurance program beneficiaries in a teaching hospital is determined on the basis of an average per diem, as defined in paragraph (h)(1) of this section, for physicians' direct medical and surgical services to all patients except that the average per diem will be derived from the imputed value of the physician volunteer direct medical and surgical services rendered to all patients.

(h) *Definitions*—(1) *Average cost per diem for physicians' direct medical and surgical services (including supervision of interns and residents) rendered in a teaching hospital.* Average cost per diem for physicians' direct medical and surgical services rendered in a teaching hospital to patients in each category of physicians' services as described in paragraphs (g)(1) (i) and (ii) of this section means the amount computed by dividing total reasonable costs of such services in each category by the sum of:

(i) Inpatient days (as defined in paragraph (h)(2) of this section) and,

(ii) Outpatient visit days (as defined in paragraph (h)(3) of this section).

(2) *Inpatient days.* Inpatient days will be determined by counting the day of admission as 3.5 days and each day subsequent to a patient's day of admission except the day of discharge, as 1 day.

(3) *Outpatient visit days.* Outpatient visit days will be determined by counting only one visit day for each calendar day that a patient visits the outpatient department.

(i) *Application.* (1) The following illustrates how apportionment based on the Aggregate Per Diem Method for cost of physicians' direct medical and surgical services rendered in a teaching hospital to patients will be determined.

TEACHING HOSPITAL Y

Statistical and financial data:	
Total inpatient days as defined in paragraph (h)(2) of this section and outpatient visit days as defined in paragraph (h)(3) of this section	75,000
Total inpatient part A days applicable to program beneficiaries	20,000

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TEACHING HOSPITAL Y—Continued

Total inpatient part B days applicable to program beneficiaries where part A coverage is not available	1,000
Total outpatient part B visit days applicable to program beneficiaries	5,000
Total cost of direct medical and surgical services rendered to all patients by physicians on the hospital staff as determined in accordance with paragraph (j) of this section	$1,500,000
Total cost of direct medical and surgical services rendered to all patients by physicians on the medical school faculty as determined in accordance with paragraph (j) of this section	$1,650,000
Computation of cost applicable to program for physicians on the hospital staff:	
Average cost per diem for direct medical and surgical services to patients by physicians on the hospital staff: $1,500,000 ÷ 75,000 = $20 per diem.	
Cost of physicians' direct medical and surgical services rendered to inpatient beneficiaries covered under part A: $20 per diem × 20,000	$400,000
Cost of physicians' direct medical and surgical services rendered to inpatient beneficiaries covered under part B: $20 per diem × 1,000	$20,000
Cost of physicians' direct medical and surgical services rendered to outpatient beneficiaries covered under part B: $20 per diem × 5,000	$100,000
Computation of cost applicable to program for physicians on the medical school faculty:	
Average cost per diem for direct medical and surgical services to patients by physicians on the medical school faculty: $1,650,000 ÷ 75,000 = $22 per diem.	
Cost of physicians' direct medical and surgical services rendered to inpatient beneficiaries covered under part A: $22 per diem × 20,000	$440,000
Cost of physicians' direct medical and surgical services rendered to inpatient beneficiaries covered under part B: $22 per diem × 1,000	$22,000
Cost of physicians' direct medical and surgical services rendered to outpatient beneficiaries covered under part B: $22 per diem × 5,000	$110,000

(2) The following illustrates how the imputed value of physicians' volunteer direct medical and surgical services rendered in a teaching hospital applicable to health insurance program patients will be determined.

Example: The physicians on the medical staff of Teaching Hospital Y donated a total of 5,000 hours in rendering direct medical and surgical services to patients of the hospital during a cost-reporting period and did not receive any compensation from either the hospital or the medical school. Also, the imputed value for any physician's volunteer services did not exceed the rate of $30,000 per year per physician.

Statistical and financial data:	
Total salaries paid to the full-time salaried physicians by the hospital (excluding interns and residents)	$800,000
Total physicians who were paid for an average of 40 hours per week or 2,080 (52 weeks × 40 hours per week) hours per year	20
Average hourly rate equivalent: $800,000 ÷ 41,600 (2,080 × 20)	$19.23
Computation of total imputed value of physicians' volunteer services applicable to all patients:	
(Total donated hours × average hourly rate equivalent): 5,000 × $19.23	$96,150
Total inpatient days (as defined in paragraph (h)(2) of this section) and outpatient visit days (as defined in paragraph (h)(3) of this section)	75,000
Total inpatient part A days applicable to program beneficiaries	20,000
Total inpatient part B days applicable to program beneficiaries where part A coverage is not available	1,000
Total outpatient part B visit days applicable to program beneficiaries	5,000
Computation of imputed value of physicians' volunteer direct medical and surgical services applicable to program beneficiaries:	
Average per diem for physicians' direct medical and surgical services to patients: $96,150 ÷ 75,000 = $1.28 per diem.	
Imputed value of physicians' direct medical and surgical services rendered to inpatient beneficiaries covered under part A: $1.28 per diem × 20,000	$25,600
Imputed value of physicians' direct medical and surgical services rendered to inpatient beneficiaries covered under part B: $1.28 per diem × 1,000	$1,280
Imputed value of physicians' direct medical and surgical services rendered to outpatient beneficiaries covered under part B: $1.28 per diem × 5,000	$6,400
Total	$33,280

(j) *Allocation of compensation paid to physicians in a teaching hospital.* In determining reasonable cost under this section, the compensation paid by a teaching hospital, or a medical school or related organization under arrangement with the hospital, to physicians in a teaching hospital must be allocated to the full range of services implicit in the physicians' compensation arrangements. (However, see paragraph (d) of this section for the computation of the "salary equivalent" payments for volunteer services rendered to patients.) Such allocation must be made and must be capable of substantiation on the basis of the proportion of each physician's time spent in rendering each type of service to such hospital and/or medical school.

[40 FR 33440, Aug. 8, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 34792, Sept. 30, 1986]

§ 405.466 Payment to a fund.

(a) *General.* Payment for certain voluntary services by physicians in teaching hospitals (as such services are described in § 405.521(d)(2) will be paid on a salary equivalent basis (as described in § 405.465(d)) subject to the conditions and limitations contained in this Part 405 and title XVIII of the Act, to a single fund (as defined in paragraph (b) of this section) designated by the organized medical staff of the hospital (or, where such services are furnished in such hospital by the faculty of a medical school, to such fund as may be designated by the faculty), if:

(1) The hospital (or medical school furnishing the services under arrangement with the hospital) incurs no actual cost in furnishing the services; and

(2) The hospital has an agreement with the Secretary under § 405.602; and

(3) The intermediary, or the Health Care Financing Administration, as appropriate, has received written assurances that:

(i) The payment will be used solely for the improvement of care of hospital patients or for educational or charitable purposes; and

(ii) Neither the individuals who are furnished the services nor any other persons will be charged for the services (and if charged, provision will be made for the return of any monies incorrectly collected).

(b) *Definition of a fund.* For purposes of paragraph (a) of this section, a fund is an organization which meets either of the following requirements:

(1) Has and retains exemption, as a governmental entity or under section 501(c)(3) of the Internal Revenue Code (nonprofit educational, charitable, and similar organizations), from Federal taxation; or

(2) Is an organization of physicians who, under the terms of their employment by an entity which meets the requirements of paragraph (b)(1) of this section, are required to turn over to that entity all income which the physician organization derives from the physicians' services.

(c) *Status of a fund.* A fund approved for payment under paragraph (a) of this section has all the rights and responsibilities of a provider under title XVIII of the Act except that it does not enter into an agreement with the Secretary under § 405.602.

[40 FR 33443, Aug. 8, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

PAYMENT FOR SERVICES OF PHYSICIANS TO PROVIDERS

§ 405.480 Payment for services of physicians to providers: General rules.

(a) *Allowable Costs.* Except as specified otherwise in § 413.102 of this chapter, § 405.465, or § 405.466, costs a provider incurs for services of physicians are allowable only if the following conditions are met:

(1) The services do not meet the conditions in § 405.550(b) regarding reasonable charge reimbursement for services of physicians to an individual patient of a provider;

(2) The services do not include physician availability services, except for reasonable availability services furnished for emergency rooms;

(3) The provider has incurred a cost for salary or other compensation it furnished the physician for the services; and

(4) The costs incurred by the provider for the services meet the requirements in § 413.9 of this chapter regarding costs related to patient care.

(b) *Allocation of costs.* In determining its costs of services that meet the conditions for payment in paragraph (a) of this section, the provider must follow the rules in § 405.481 regarding allocation of physician compensation costs.

(c) *Limits on allowable costs.* In determining its payments to a provider for the costs of services that meet the conditions for payment in paragraph (a) of this section, the intermediary must apply the limits on compensation set forth in § 405.482.

[48 FR 8935, Mar. 2, 1983, as amended at 51 FR 34792, Sept. 30, 1986]

§ 405.481 Allocation of physician compensation costs.

(a) *Definition.* For purposes of this subpart, "physician compensation costs" means monetary payments, fringe benefits, deferred compensation and any other items of value (excluding office space or billing and collection services), a provider or other organization furnishes a physician in return for the physician's services. Other organizations are entities related to the provider within the meaning of § 413.17 of this chapter, or entities that furnish services for the provider "under arrangements" within the meaning of the Act.

(b) *General rule on allocation of physician compensation costs.* Except as provided in paragraph (d) of this section, each provider that incurs physician compensation costs must allocate those costs, in proportion to the percentage of total time that is spent in furnishing each category of services, between:

(1) Physician services to the provider (as described in § 405.480);

(2) Physician services to patients (as described in § 405.550); and

(3) Activities of the physician, such as funded research, that are not reimbursable under either Part A or Part B of Medicare.

(c) *Allowable physician compensation costs.* Only costs allocated to reimbursable physician services to the provider (as described in § 405.480) are allowable costs to the provider under this subpart.

(d) *Allocation of all compensation to services to the provider.* Generally, the total physician compensation received by a physician will be allocated among all services furnished by the physician, unless:

(1) The provider certifies that the compensation is attributable solely to the physician's services to the provider; and

(2) The physician bills all of his or her patients for the physician services he or she furnishes to those patients and personally receives the payment from such billings. If returned directly or indirectly to the provider or an organization related to the provider within the meaning of § 413.17 of this chapter, these payments are not compensation for physician services to the provider.

(e) *Assumed allocation of all compensation to patient services.* If the provider and physician agree to accept the assumed allocation of all the physician's services to direct services to individual patients as described under § 405.550(b), a written allocation agreement is not required.

(f) *Determination and payment of allowable physician compensation costs.* (1) Except as provided under paragraph (e) of this section, the intermediary will reimburse the provider for these costs only if:

(i) The provider submits to the intermediary a written allocation agreement between the provider and the physician that specifies the respective amounts of time the physician spends in furnishing physician services to the provider, physician services to patients, and services that are not reimbursable under either Part A or Part B of Medicare; and

(ii) The compensation is reasonable in terms of the time devoted to these services.

(2) In the absence of a written allocation agreement, the intermediary will assume, for purposes of determining reasonable costs of the provider, that 100 percent of the physician's compensation cost is allocated to services to patients as specified in paragraph (b)(2) of this section.

(g) *Recordkeeping requirements.* Except for services furnished in accordance with the assumed allocation under paragraph (e) of this section, each provider that claims payment for services of physicians under this subpart must:

(1) Maintain the time records or other information it used to allocate physician compensation in a form that permits the information to be validated by the intermediary or the carrier;

(2) Report the information on which the physician compensation allocation is based to the intermediary or the carrier on an annual basis, and promptly notify the intermediary or carrier of any revisions to the compensation allocation; and

(3) Retain each physician compensation allocation, and the information on which it is based, for at least four

years after the end of each cost reporting period to which the allocation applies.

[48 FR 8936, Mar. 2, 1983, as amended at 51 FR 34792, Sept. 30, 1986]

§ 405.482 Limits on compensation for services of physicians in providers.

(a) *Principle and scope.* (1) Except as provided in paragraphs (a) (2) and (3) of this section, HCFA will establish reasonable compensation equivalent (RCE) limits on the amount of compensation paid to physicians by providers. These limits will be applied to a provider's costs incurred in compensating physicians for services to the provider, as described in § 405.480(a).

(2) Limits established under this section will not apply to costs of physician compensation attributable to furnishing inpatient hospital services that are paid for under the prospective payment system implemented under Part 412 of this chapter.

(3) Compensation that a physician receives for activites that may not be paid for under either Part A or Part B of Medicare will not be considered in applying these limits.

(b) *Methodology for establishing limits.* HCFA will establish a methodology for determining reasonable annual compensation equivalents, considering average physician incomes by specialty and type of location, to the extent possible using the best available data.

(c) *Application of limits.* If the level of compensation exceeds the limits established under paragraph (b) of this section, Medicare payment will be based on the level established by the limits.

(d) *Adjustment to the limits.* The intermediary may adjust limits established under paragraph (b) of this section to account for costs incurred by the physician or the provider related to malpractice insurance, professional memberships, and continuing medical education.

(1) For the costs of membership in professional societies and continuing medical education, the intermediary may adjust the limit by the lesser of:

(i) The actual cost incurred by the provider or the physician for these activities; or

(ii) 5 percent of the appropriate limit.

(2) For the cost of malpractice expenses incurred by either the provider or the physician, the intermediary may adjust the reasonable compensation limit by the cost of the malpractice insurance expense related to the physician's service to provider patients.

(e) *Exception to limits.* An intermediary may grant a provider an exception to the limits established under paragraph (b) of this section only if the provider can demonstrate to the intermediary that it is unable to recruit or maintain an adequate number of physicians at a compensation level within those limits.

(f) *Notification of changes in methodologies and payment limits.* (1) Before the start of a cost reporting period to which limits established under this section will be applied, HCFA will publish a notice in the FEDERAL REGISTER that sets forth the amount of the limits and explains how the limits were calculated.

(2) If HCFA proposes to revise the methodology by which payment limits under this section are established, HCFA will publish a notice, with opportunity for public comment, to that effect in the FEDERAL REGISTER. The notice would explain the proposed basis for setting limits, specify the limits that would result, and state the date of implementation of the limits.

(3) Revised limits updated by applying the most recent economic index data without revision of the limit methodology will be published in a notice in the FEDERAL REGISTER without prior publication of a proposal or public comment period.

[48 FR 8936, Mar. 2, 1983, as amended at 48 FR 39829, Sept. 1, 1983]

Subpart E—Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians

AUTHORITY: Secs. 1102, 1814(b), 1832, 1833(a), 1842 (b) and (h), 1861 (b) and (v), 1862(a)(14), 1866(a), 1871, 1881, 1886, 1887, and 1889 of the Social Security Act as amended (42 U.S.C. 1302, 1395f(b), 1395k, 1395l(a), 1395u (b) and (h), 1395x (b) and (v), 1395y(a)(14), 1395cc(a), 1395hh, 1395rr, 1395ww, 1395xx, and 1395zz).

SOURCE: 32 FR 12599, Aug. 31, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.501 Determination of reasonable charges.

(a) Except as specified in paragraph (b) of this section, Medicare pays no more for Part B medical and other health services than the "reasonable charge" for such service. The reasonable charge is determined by the carriers (subject to any deductible and coinsurance amounts as specified in §§ 410.152 and 410.160 of this chapter).

(b) Part B of Medicare pays on the basis of "reasonable cost" (see Part 413 of this chapter) for certain institutional services, certain services furnished under arrangements with institutions, and services furnished by entities that elect to be paid on a cost basis (including health maintenance organizations, rural health clinics, and end-stage renal disease facilities).

(c) Carriers will determine the reasonable charge on the basis of the criteria specified in § 405.502, and the customary and prevailing charge screens in effect when the service was furnished. (Also see §§ 405.480 through 405.482 and §§ 405.550 through 405.557, which pertain to the determination of reimbursement for services performed by hospital-based physicians.) However, when services are furnished more than 12 months before the beginning of the fee screen year (January 1 through December 30) in which a request for payment is made, payment is based on the customary and prevailing charge screens in effect for the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is made.

[47 FR 63274, Dec. 31, 1981, as amended at 51 FR 34792, Sept. 30, 1986; 51 FR 34978, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986; 51 FR 41351, Nov. 14, 1986]

§ 405.502 Criteria for determining reasonable charges.

(a) *Criteria.* The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:

(1) The customary charges for similar services generally made by the physician or other person furnishing such services.

(2) The prevailing charges in the locality for similar services.

(3) In the case of physicians' services, the prevailing charges for such services for fiscal year 1973 adjusted to reflect the cumulative economic index since calendar year 1971 but only if the charges so determined are not more than the prevailing charges determined under § 405.504(a)(2). The data used in determining the cumulative economic index should reflect changes in expenses of physicians' office practice and in general earnings levels.

(4) In the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services), the inflation-indexed charge as determined under § 405.509.

(5) [Reserved]

(6) In the case of medical services, supplies, and equipment (including equipment servicing) that the Secretary judges do not generally vary significantly in quality from one supplier to another, the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality.

(7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by HCFA or a carrier if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in the grossly deficient or excessive charges. The determination of these limits is described in paragraphs (g) and (h) of this section.

(8) In the case of laboratory services billed by a physician but performed by an outside laboratory, the payment

levels established in accordance with the criteria stated in § 405.515.

(9) Except as provided in paragraph (a)(10) of this section, in the case of services of assistants at surgery as defined in § 405.580 in teaching and nonteaching settings, charges that are not more than 20 percent of the prevailing charge in the locality, adjusted by the economic index, for the surgical procedure performed by the primary surgeon.

(10) In the case of services of assistants at surgery that meet the exception under § 405.580(c) (2) or (3) because the physician is performing a unique, necessary, specialized medical service in the total care of a patient during surgery, reasonable charges consistent with prevailing practice in the carrier's service area rather than the special assistant at surgery rate.

(b) *Comparable services limitation.* The law also specifies that the reasonable charge cannot be higher than the charge applicable for a comparable service under comparable circumstances to the carriers' own policyholders and subscribers.

(c) *Application of criteria.* In applying these criteria, the carriers are to exercise judgment based on factual data on the charges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable.

(d) *Responsibility of Administration and carriers.* Determinations by carriers of reasonable charge are not reviewed on a case-by-case basis by the Health Care Financing Administration, although the general procedures and performance of functions by carriers are evaluated. In making determinations, carriers apply the provisions of the law under broad principles issued by the Health Care Financing Administration. These principles are intended to assure overall consistency among carriers in their determinations of reasonable charge. The principles in §§ 405.503 through 405.507 establish the criteria for making such determinations in accordance with the statutory provisions.

(e) *Determination of reasonable charges under the End-Stage Renal Disease (ESRD) Program*—(1) *General.* Reasonable charges for renal-related items and services (furnished in connection with transplantation or dialysis) must be related to costs and allowances that are reasonable when the treatments are furnished in an effective and economical manner.

(2) *Nonprovider (independent) dialysis facilities.* Reasonable charges for renal-related items and services furnished before August 1, 1983 must be determined related to costs and charges prior to July, 1973, in accordance with the regulations at § 405.541. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(3) *Provider services and (hospital-based) dialysis facilities.* Renal-related items and services furnished by providers, or by ESRD facilities based in hospitals, before August 1, 1983 are paid for under the provider reimbursement provisions found generally in Part 413 of this chapter. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(4) *Physicians' services.* Reasonable charges for renal-related physicians' services must be determined considering charges made for other services involving comparable physicians' time and skill requirements, in accordance with regulations at §§ 405.542 and 405.543.

(5) *Health maintenance organizations (HMOs).* For special rules concerning the reimbursement of ESRD services furnished by risk-basis HMOs, or by facilities owned or operated by or related to such HMOs by common ownership or control, see §§ 405.2042(b)(14) and 405.2050(c).

(f) *Determining charge payments for certain physician services furnished in outpatient settings*—(1) *General rule.* If physician services of the type routinely furnished in physicians' offices are furnished in outpatient settings, carriers determine the reasonable charge for those services by applying the limits described in paragraph (f)(5) of this section.

(2) *Definition.* As used in this paragraph (f), *"outpatient settings"* means—

(i) Hospital outpatient departments, including clinics and emergency rooms; and

(ii) Comprehensive outpatient rehabilitation facilities.

(3) *Services covered by limits.* The carrier establishes a list of services routinely furnished in physicians' offices in the area. The carrier has the discretion to determine which professional services are routinely furnished in physicians' offices, based on current medical practice in the area. Listed below are some examples of routine services furnished by office-based physicians.

Examples

Review of recent history, determination of blood pressure, ausculation of heart and lungs, and adjustment of medication.

Brief history and examination, and initiation of diagnostic and treatment programs.

Treatment of an acute respiratory infection.

(4) *Services excluded from limits.* The limits established under this paragraph do not apply to the following:

(i) Rural health clinic services.

(ii) Surgical services included on the ambulatory surgical center list of procedures published under § 416.65(c) of this chapter.

(iii) Services furnished in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the patient's health in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(iv) Anesthesiology services and diagnostic and therapeutic radiology services.

(5) *Methodology for developing limits*—(i) *Development of a charge base.* The carrier establishes a charge base for each service identified as a routine office-based physician service. The charge base consists of the prevailing charge in the locality for each such service adjusted by the economic index. The carrier uses the prevailing charges that apply to services by nonspecialists in office practices in the locality in which the outpatient setting is located.

(ii) *Calculation of the outpatient limits.* The carrier calculates the charge limit for each service by multiplying the charge base amount for each service by .60.

(6) *Application of limits.* The reasonable charge for physician services of the type described in paragraph (f)(3) of this section that are furnished in an outpatient setting is the lowest of the actual charges, the customary charges in accordance with § 405.503, the prevailing charges applicable to these services in accordance with § 405.504, or the charge limits calculated in paragraph (f)(5)(ii) of this section.

(g) *Determination of reasonable charges in special circumstances: General.* HCFA or a carrier may establish special reasonable charge limits for a category of service if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in grossly deficient or excessive charges. The limit on the reasonable charge is an upper limit to correct a grossly excessive charge or a lower limit to correct a grossly deficient charge. The limit is either a specific dollar amount, or is based on a special method to be used in determining the reasonable charge.

(1) *Determination of excessive or deficient charges.* HCFA or a carrier may make a determination that the standard rules for calculating reasonable charges set forth in this subpart result in grossly deficient or excessive charges. HCFA's determination may apply to the services of any supplier; however, a carrier's determination may apply only to nonphysician services. Examples of the circumstances which may result in grossly deficient or excessive charges include, but are not limited to the following:

(i) The marketplace is not competitive. This includes circumstances in which the marketplace for a service is not truly competitive because a limited number of physicians perform the service.

(ii) Medicare and Medicaid are the sole or primary sources of payment for a service.

(iii) The charges involve the use of new technology for which an extensive charge history does not exist.

(iv) The charges do not reflect changing technology, increased facility with that technology, or changes in acquisition, production or supplier costs.

(v) The prevailing charges for a service in a particular locality are significantly in excess of or below prevailing charges in other comparable localities, taking into account the relative costs of furnishing the services in the different localities.

(vi) Charges are grossly lower than or in excess of acquisition or production costs.

(vii) There have been increases in charges for a service that cannot be explained by inflation or technology.

(viii) The prevailing charges for a service are substantially higher or lower than the payments made for the service by other purchasers in the same locality.

(2) *Establishing a limit.* In establishing a limit, HCFA or a carrier considers the available information that is relevant to the category of service and establishes a reasonable charge that is realistic and equitable. The factors to be considered in establishing a specific dollar amount or special method may include the following:

(i) *Price markup.* This is the relationship between the retail and wholesale prices or manufacturer's costs of a category of service. If information on a particular category of service is not available, HCFA or a carrier may consider the markup on similar services and information on general industry pricing trends.

(ii) *Differences in charges.* HCFA or a carrier may consider the differences in charges to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* HCFA or a carrier may consider resources (overhead, time, acquisition costs, production costs, complexity, etc.) required to produce a service or a product.

(iv) *Utilization.* HCFA or a carrier may impute a reasonable rate of use for a category of service and consider unit costs based on efficient utilization.

(v) *Charges in other localities.*

(vi) *Other relevant factors.*

(3) *Notification of limits*—(i) *National limits.* When HCFA makes a determination regarding nonphysicians' services under this section, it publishes in the Federal Register proposed and final notices of a special reasonable charge limit before the limit is adopted. The notice sets forth in the Federal Register the criteria and circumstances, if any, under which a carrier may grant an exception to the limit.

(ii) *Carrier level limits.* After September 9, 1988, a carrier proposing to establish a generally applicable special reasonable charge limit must inform the affected suppliers and State Medicaid agencies of the factors considered in establishing the limit as described in paragraphs (g) (1) and (2) of this section and solicit comments. After evaluating the comments received, the carrier must inform the affected suppliers and State Medicaid agencies of any final limit established. The limit is effective for services furnished no fewer than 30 days after the date of the carrier's notification.

(h) *Determination of reasonable charges in special circumstances: Physician services.* In establishing special reasonable charge limits for a category of physician services, HCFA applies the general rules under paragraphs (g) (1) and (2) of this section and the following special rules:

(1) *Potential impact of special limit.* In determining whether to set a special reasonable charge limit for a category of physician service, HCFA considers the potential impact on quality, access, beneficiary liability, assignment rates, reasonable charge reductions on unassigned claims, and participation rates of physicians.

(2) *Physician consultation.* Before making a determination that a charge is not inherently reasonable by reason of its grossly excessive or deficient amount, HCFA consults with representatives of the physicians likely to be affected by any change in the reasonable charge.

(3) *Special limits based on comparison of charges in different localities.* HCFA takes into account differences in practice costs before basing a special limit on the comparison of prevailing charges in different localities.

(4) *Factors considered in establishing a special limit.* (i) In establishing the specific dollar amount or special method under paragraph (g)(2) of this section, HCFA takes into account regional differences in fees unless there is substantial economic justification, as described in the proposed and final notices required under paragraphs (h)(5) (i) and (ii) of this section, for a uniform fee or a uniform payment limit.

(ii) In determining that a charge is not inherently reasonable by reason of its grossly excessive or deficient amount, and in establishing the specific dollar amount or special method under paragraphs (g) (1) and (2) of this section, HCFA may compare the charge to the—

(A) Resource costs (that is, factors such as the time required to provide a procedure, including pre-procedure evaluation and post-procedure follow-up; the complexity of the procedure; the training required to perform the procedure; and the risk involved in the procedure) for related services;

(B) Resource costs for the service over a period of time;

(C) Charges for the service in different geographic areas after accounting for differences in practice costs;

(D) Payments for a service allowed under Medicare Part B and by other payors; and

(E) Other relevant factors.

(5) *Publication of national limits.* When HCFA makes a determination under this section, it publishes in the FEDERAL REGISTER proposed and final notices of a special reasonable charge limit before the limit is adopted. The notice sets forth in the FEDERAL REGISTER the criteria and circumstances, if any, under which a carrier may grant an exception to the limit.

(i) *Proposed notice.* The proposed notice—

(A) Specifies the proposed charge or methodology to be established with respect to a service;

(B) Explains the factors and data that HCFA took into account in determining the charge or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(C) Explains the potential impacts of a limit on physicians' services as described in paragraph (h)(1) of this section; and

(D) Allows no less than 60 days for public comment on the proposal.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that HCFA took into consideration, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments and any comments made by the Physician Payment Review Commission.

(Secs. 1102, 1814(b), 1833(a), 1842(b), and (h), and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, as amended, 79 Stat. 296, 302, 310, 331; 86 Stat. 1395, 1454; 42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1))

[32 FR 12599, Aug. 31, 1967]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 405.502, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 405.503 Determining customary charges.

(a) *Customary charge defined.* The term "customary charges" will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service. In determining such uniform amount, token charges for charity patients and substandard charges for welfare and other low income patients are to be excluded. The reasonable charge cannot, except as provided in § 405.506, be higher than the individual physician's or other person's customary charge. The customary charge for different physicians or other persons may, of course, vary. Payment for covered services would be based on the actual charge for the service when, in a given instance, that charge is less than the amount which the carrier would otherwise have found to be within the limits of acceptable charges for the particular service. Moreover, the income of the individual beneficiary is not to be taken into account by the carrier in determining the amount which is considered to be a reasonable charge for a service rendered to him. There is no provision in the law for a carrier to evaluate the reasonableness of charges in light of an individual beneficiary's economic status.

(b) *Variation of charges.* If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a "customary charge" for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's "customary" charge. Use of relative value scales will help in arriving at a decision in such instances.

(c) *Use of relative value scales.* If, for a particular medical procedure or service, the carrier is unable to determine the customary charge on the basis of reliable statistical data (for example, because the carrier does not yet have sufficient data or because the performance of the particular medical procedure or service by the physician or other person is infrequent), the carrier may use appropriate relative value scales to determine the customary charge for such procedure or service in relation to customary charges of the same physician or person for other medical procedures and services.

(d) *Revision of customary charge.* A physician's or other person's customary charge is not necessarily a static amount. Where a physician or other person alters his charges, a revised pattern of charges for his services may develop. Where on the basis of adequate evidence, the carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered thereafter to supplementary insurance beneficiaries. If the new customary charge is not above the top of the range of prevailing charges (see § 405.504(a)), it should be deemed to be reasonable by the carrier, subject to the provisions of § 405.508.

§ 405.504 Determining prevailing charges.

(a) *Ranges of charges.* (1) In the case of physicians' services furnished beginning January 1, 1987, the prevailing charges for a nonparticipating physician as defined in this paragraph will be no higher than the same level that was set for services furnished during the previous calendar year for a physician who was a participating physician during that year. A nonparticipating physician is a physician who has not entered into an agreement with the Medicare program to accept payment on an assignment-related basis (in accordance with § 424.55 of this chapter) for all items and services furnished to individuals enrolled under Part B of Medicare during a given calendar year.

(2) No charge for Part B medical or other health services may be considered to be reasonable if it exceeds the higher of:

(i) The prevailing charge for similar services in the same locality in effect on December 31, 1970, provided such prevailing charge had been found acceptable by HCFA; or

(ii) The prevailing charge that, on the basis of statistical data and methodology acceptable to HCFA, would cover:

(A) 75 percent of the customary charges made for similar services in the same locality during the 12-month period of July 1 through June 30 preceding the fee screen year (January 1 through December 31) in which the service was furnished; or

(B) In the case of services furnished more than 12 months before the beginning of the fee screen year (January 1 through December 31) in which the claim or request for payment is submitted. 75 percent of the customary charges made for similar services in the same locality during the 12 month period of July 1 through June 30 preceding the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is submitted.

(3)(i) In the case of physicians' services, each prevailing charge in each locality may not exceed the prevailing charge determined for the fiscal year ending June 30, 1973 (without reference to the adjustments made pursuant to the economic stabilization program then in effect), except on the basis of appropriate economic index data which demonstrate that such higher prevailing charge level is justified by:

(A) Changes in general earnings levels of workers that are attributable to factors other than increases in their productivity; and (B) changes in expenses of the kind incurred by physicians in office practice. The office-expense component and the earnings component of such index shall be given the relative weights shown in data on self-employed physicians' gross incomes.

Example. The available data indicate the office-expense and earnings components of the index should be given relative weights of 40 percent and 60 percent, respectively, and it is calculated that the aggregate increase in expenses of practice for a particular July through June period was 112 percent over the expenses of practice for calendar year 1971 and the increase in earnings (less increases in workers' productivity was 110 percent over the earnings for calendar year 1971. The allowable increase in any prevailing charge that could be recognized during the next fee screen year would be 110.8 percent ((.40×112)+(.60)×110)=110.8) above the prevailing charge recognized for fiscal year 1973.

(ii)(A) If the increase in the prevailing charge in a locality for a particular physician service resulting from an aggregate increase in customary charges for that service does not exceed the index determined under paragraph (a)(3)(i) of this section, the increase is permitted and any portion of the allowable increase not used is carried forward and is a basis for justifying increases in that prevailing charge in the future. However, if the increase in the prevailing charge exceeds the allowable increase, the increase will be reduced to the allowable amount. Further increases will be justified only to the degree that they do not exceed further rises in the economic index. The prevailing charge for physicians' services furnished during the 15-month period beginning July 1, 1984 may not exceed the prevailing charge for physicians' services in effect for the 12-month period beginning July 1, 1983. The increase in prevailing charges for physicians' services for subsequent fee screen years similarly may not reflect the rise in the economic index that would have otherwise been provided for the period beginning July 1, 1984, and must be treated as having fully provided for the rise in the economic index which would have been otherwise taken into account.

(B) Notwithstanding the provisions of paragraphs (a)(3)(i) and (ii)(A) of this section, the prevailing charge in the case of a physician service in a particular locality determined pursuant to paragraphs (a)(2) and (3)(i) of this section for the fiscal year beginning July 1, 1975, and for any subsequent fee screen years, if lower than the prevailing charge for the fiscal year ending June 30, 1975, by reason of the application of economic index data, must be raised to such prevailing charge which was in effect for the fiscal year ending June 30, 1975. (If the amount paid on any claim processed by a carrier after the original reasonable charge update for the fiscal year beginning July 1, 1975, and prior to the adjustments required by the preceding sentence, was at least $1 less than the amount due pursuant to the preceding sentence, the difference between the amount previously paid and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously paid and the amount due is less that $1.)

(iii) When, for any reason, a prevailing charge for a service in a locality has no precise counterpart in the carrier's charge date for calendar year 1971 (the data on which the prevailing charge calculations for fiscal year 1973 were based), the limit on the prevailing charge shall be estimated, on the basis of data and methodology acceptable to the Secretary, to seek to produce the effect intended by the economic index criterion. The allowance or reduction of an increase in a prevailing charge for any individual medical item or service may affect the allowance or reduction of an increase in the prevailing charges for other items or services where, for example, the limit on the prevailing charge is estimated as explained in the preceding sentence of this section, or where the prevailing charges for more than one item or service are established through the use of a relative value schedule and of dollar conversion factors.

(b) *Variation in range of prevailing charges.* The range of prevailing charges in a locality may be different for physicians or other persons who engage in a specialty practice or service than for others. Existing differentials in the level of charges between different kinds of practice or service could, in some localities, lead to the development of more than one range of prevailing charges for application by the carrier in its determinations of reasonable charges. Carrier decisions in this respect should be responsive to the existing patterns of charges by physicians and other persons who render covered services, and should establish differentials in the levels of charges between different kinds of practice or service only where in accord with such patterns.

(c) *Re-evaluation and adjustment of prevailing charges.* Determinations of prevailing charges by the carrier are to be re-evaluated and adjusted from time to time on the basis of factual information about the charges made by physicians and other persons to the public in general. This information should be obtained from all possible sources including a carrier's experience with its own programs as well as with the supplementary medical insurance program.

[32 FR 12600, Aug. 31, 1967, as amended at 40 FR 25447, June 16, 1975; 42 FR 18275, Apr. 6, 1977. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 4430, Feb. 2, 1978; 47 FR 63274, Dec. 31, 1982; 51 FR 34978, Oct. 1, 1986; 53 FR 6648, Mar. 2, 1988]

§ 405.505 Determination of "locality."

"Locality" is the geographical area for which the carrier is to derive the prevailing charges for services. Usually, a locality will be a political or economic subdivision of a State. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical service areas (interstate or otherwise), comparable in concept to "trade areas." Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore shall delineate "localities" on the basis of their knowledge of local conditions. However, distinctions between localities are not to be so finely made that a "locality" includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

§ 405.506 Charges higher than customary or prevailing charges or lowest charge levels.

A charge which exceeds the customary charge of the physician or other person who rendered the medical or other health service, or the prevailing charge in the locality, or an applicable lowest charge level may be found to be reasonable, but only where there are unusual circumstances, or medical complications requiring additional time, effort or expense which support an additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. The mere fact that the physician's or other person's customary charge is higher than prevailing would not justify a determination that it is reasonable.

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331; 86 Stat. 1395, 1454; (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978]

§ 405.507 Illustrations of the application of the criteria for determining reasonable charges.

The following examples illustrate how the general criteria on customary charges and prevailing charges might be applied in determining reasonable charges under the supplementary medical insurance program. Basically, these examples demonstrate that, except where the actual charge is less, reasonable charges will reflect current customary charges of the particular physician or other person within the ranges of the current prevailing charges in the locality for that type and level of service:

The prevailing charge for a specific medical procedure ranges from $80 to $100 in a certain locality.

Doctor A's bill is for $75 although he customarily charges $80 for the procedure.

Doctor B's bill is his customary charge of $85

Doctor C's bill is his customary charge of $125

Doctor D's bill is for $100, although he customarily charges $80, and there are no special circumstances in the case.

The reasonable charge for Doctor A would be limited to $75 since under the law the reasonable charge cannot exceed the actual charge, even if it is lower than his customary charge and below the prevailing charges for the locality.

The reasonable charge for Doctor B would be $85, because it is his customary charge and it falls within the range of prevailing charges for that locality.

The reasonable charge for Doctor C could not be more than $100, the top of the range of prevailing charges.

The reasonable charge for Doctor D would be $80, because that is his customary charge. Even though his actual charge of $100 falls within the range of prevailing charges, the reasonable charge cannot exceed his customary charge in the absence of special circumstances.

§ 405.508 Determination of comparable circumstances; limitation.

(a) *Application of limitation.* The carrier may not in any case make a determination of reasonable charge which would be higher than the charge upon which it would base payment to its own policyholders for a comparable service in comparable circumstances. The charge upon which it would base payment, however, does not necessarily mean the amount the carrier would be obligated to pay. Under certain circumstances, some carriers pay amounts on behalf of individuals who are their policyholders, which are below the customary charges of physicians or other persons to other individuals. Payment under the supplementary medical insurance program would not be limited to these lower amounts.

(b) *When comparability exists.* "Comparable circumstances," as used in the Act and this subpart, refers to the circumstances under which services are rendered to individuals and the nature of the carrier's health insurance programs and the method it uses to determine the amounts of payments under these programs. Generally, comparability would exist where:

(1) The carrier bases payment under its program on the customary charges, as presently constituted, of physicians or other persons and on current prevailing charges in a locality, and

(2) The determination does not preclude recognition of factors such as speciality status and unusual circumstances which affect the amount charged for a service.

(c) *Responsibility for determining comparability.* Responsibility for determining whether or not a carrier's program has comparability will in the first instance fall upon the carrier in reporting pertinent information about its programs to the Health Care Financing Administration. When the pertinent information has been reported, the Health Care Financing Administration will advise the carrier whether any of its programs have comparability.

§ 405.509 Determining the inflation-indexed charge.

(a) *Definition.* For purposes of this section, "inflation-indexed charge" means the lowest of the fee screens used to determine reasonable charges (as determined in § 405.503 for the customary charge, § 405.504 for the prevailing charge, this section for the inflation-indexed charge, and § 405.511 for the lowest charge level) for services, supplies, and equipment reimbursed on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor, as described in paragraph (b) of this section.

(b) *Application of inflation adjustment factor to determine inflation-indexed charge.* (1) For fee screen years beginning on or after January 1, 1987, the inflation-indexed charge is determined by updating the fee screen used to determine the reasonable charges in effect on December 31 of the previous fee screen year by application of an inflation adjustment factor, that is, the annual change in the level of the consumer price index for all urban consumers, as compiled by the Bureau of Labor Statistics, for the 12-month period ending on June 30 of each year.

(2) For services, supplies, and equipment furnished from October 1, 1985 through December 31, 1986 the inflation adjustment factor is zero.

[51 FR 34979, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986]

§ 405.511 Reasonable charges for medical services, supplies, and equipment.

(a) *General rule.* (1) A charge for any medical service, supply, or equipment (including equipment servicing) that in the judgment of HCFA generally does not vary significantly in quality from one supplier to another (and that is identified by a notice published in the FEDERAL REGISTER) may not be considered reasonable if it exceeds:

(i) The customary charge of the supplier (see § 405.503);

(ii) The prevailing charge in the locality (see § 405.504);

(iii) The charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the carrier (see § 405.508);

(iv) The lowest charge level at which the item or service is widely and consistently available in the locality (see paragraph (c) of this section); or

(v) The inflation-indexed charge, as determined under § 405.509, in the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services).

(2) In the case of laboratory services, paragraph (a)(1) of this section is applicable to services furnished by physicians in their offices, by independent laboratories (see § 405.1310(a)) and to services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital. Allowance of additional charges exceeding the lowest charge level can be approved by the carrier on the basis of unusual circumstances or medical complications in accordance with § 405.506.

(b) *Public notice of items and services subject to the lowest charge level rule.* Before the Secretary determines that lowest charge levels should be established for an item or service, notice of the proposed determination will be published with an opportunity for public comment. The descriptions or specifications of items or services in the notice will be in sufficient detail to permit a determination that items or services conforming to the descriptions will not vary significantly in quality.

(c) *Calculating the lowest charge level.* The lowest charge level at which an item or service is widely and consistently available in a locality is calculated by the carrier in accordance with instructions from HCFA as follows:

(1) *For items or services furnished on or before December 31, 1986.*

(i) A lowest charge level is calculated for each identified item or service in January and July of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the second calendar quarter preceding the determination date. Accordingly, the January calculations will be based on charges for the July through September quarter of the previous calendar year, and the July calculations will be based on charges for the January through March quarter of the same calendar year.

(2) *For items or services furnished on or after January 1, 1987.*

(i) A lowest charge level is calculated for each identified item or service in January of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the 3-month period of July 1 through September 30 preceding the fee screen year (January 1 through December 31) for which the item or service was furnished.

(3) *Lowest charge levels for laboratory services.* In setting lowest charge levels for laboratory services, the carrier will consider only charges made for laboratory services performed by physicians in their offices, by independent laboratories which meet coverage requirements, and for services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital.

(d) *Locality.* Subject to the approval of the Secretary, the carrier may designate its entire service area as the locality for purposes of this section, or may otherwise modify the localities used for calculating prevailing charges. (The modified locality for an item or service will also be used for calculating the prevailing charge for that item or service.)

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331, 86 Stat. 1395, 1454 (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978, as amended at 50 FR 40174, Oct. 1, 1985; 51 FR 34979, Oct. 1, 1986]

§ 405.512 Carriers' procedural terminology and coding systems.

(a) *General.* Procedural terminology and coding systems are designed to provide physicians and third party payers with a common language that accurately describes the kinds and levels of services provided and that can serve as a basis for coverage and payment determinations.

(b) *Modification of terminology and/or coding systems.* A carrier that wishes to modify its system of procedural terminology and coding shall submit its request to the Health Care Financing Administration with all pertinent data and information for approval before the revision is implemented. The Health Care Financing Administration will evaluate the proposal in the light of the guidelines specified in paragraph (c) of this section and such other considerations as may be pertinent, and consult with the Assistant Secretary for Health. The Health Care Financing Administration will approve such a revision if it determines that the potential advantages of the proposed new system, outweigh the disadvantages.

(c) *Guidelines.* The following considerations and guidelines are taken into account in evaluating a carrier's proposal to change its system of procedural terminology and coding:

(1) The rationale for converting to the new terminology and coding;

(2) The estimated short-run and long-run impact on the cost of the health insurance program, other medical care costs, administrative expenses, and the reliability of the estimates;

(3) The degree to which the conversion to the proposed new terminology and coding can be accomplished in a way that permits full implementation of the reasonable charge criteria in accordance with the provisions of this subpart;

(4) The degree to which the proposed new terminology and coding are accepted by physicians in the carrier's area (physician acceptance is assumed only if a majority of the Medicare and non-Medicare bills and claims completed by physicians in the area and submitted to the carrier can reasonably be expected to utilize the proposed new terminology and coding);

(5) The extent to which the proposed new terminology and coding system is used by the carrier in its non-Medicare business;

(6) The clarity with which the proposed system defines its terminology and whether the system lends itself to:

(i) Accurate determinations of coverage; (ii) proper assessment of the appropriate level of payment; and (iii) meeting the carrier's or Professional Standards Review Organizations' review needs and such other review needs as may be appropriate;

(7) Compatibility of the new terminology and coding system with other systems that the carrier and other carriers may utilize in the administration of the Medicare program—e.g., its compatibility with systems and statistical requirements and with the historical data in the carrier's processing system; and

(8) Compatibility of the proposed system with the carrier's methods for determining reasonable charges for services which are identified by a single element of the terminology but which may vary in content.

[40 FR 7639, Feb. 21, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.514 Payment for durable medical equipment.

(a) *Purpose.* This section specifies criteria and procedures for making payments for the purchase or rental of new and used durable medical equipment for beneficiaries under Part B of the Medicare program. It implements section 1889 of the Act.

(b) *Definition.* "Durable medical equipment" means equipment that (1) can withstand use; (2) is primarily and customarily used to serve a medical purpose; (3) generally is not useful to a person in the absence of an illness or injury; and (4) is appropriate for use in the home.

(c) *General provisions.* (1) The Medicare program will pay for durable medical equipment under Part B on the basis of a lease-purchase, lump sum payment for purchase, or rental charges, in accordance with this paragraph and paragraphs (e) through (j) of this section.

(2) The Medicare carrier shall determine whether lease-purchase or lump sum payment for purchase is more economical or practical than rental charges, based on:

(i) The period during which the beneficiary is expected to have a medical need for the equipment, as evidenced by appropriate medical records or certification by the patient's attending physician;

(ii) The criteria for reasonable charges specified in § 405.502 of this part;

(iii) Required maintenance of the equipment;

(iv) The administrative costs for renting inexpensive items;

(v) The carrier's experience of the average length of rental for the specific equipment; and

(vi) Administrative guidelines that HCFA may issue, which may contain, for example, lists of items of durable medical equipment to be purchased, rented, or either purchased or rented depending upon the purchase price of the item or the periods of medical necessity involved.

(3) The carrier shall notify the beneficiary or supplier as promptly as possible of the method of payment and the maximum amount payable under Medicare.

(d) *Payment procedures.* The Administrator may make agreements with suppliers to establish equitable and economical procedures for payment for durable medical equipment.

(e) *Payment by lease-purchase.* (1) Except as specified in paragraph (f) of this section, the Medicare carrier shall pay for durable medical equipment on a lease-purchase basis if:

(i) Purchase of the equipment is more practical or less costly than the total reasonable rental charge for the equipment during the period it is expected to be medically needed by the beneficiary; and

(ii) A supplier reasonably available to the beneficiary will offer a lease-purchase agreement that protects against unnecessary expenditures if the medical need for the equipment ends earlier than expected and provides adequate warranties, maintenance, service and repairs.

(2) HCFA (or carriers designated by HCFA) will review proposed lease-purchase arrangements offered by suppliers and approve those that comply with paragraph (e)(1)(ii) of this section. HCFA will also encourage suppliers to develop and offer lease-purchase arrangements. (For example, HCFA will furnish information to beneficiaries regarding suppliers willing to enter into practical lease-purchase agreements.)

(f) *Lump sum payment for purchase.* (1) The carrier shall pay for purchase of durable medical equipment by lump sum if:

(i) Purchase is more practical or less costly than the total expected reasonable rental charge; and

(ii) A more equitable and economical lease-purchase agreement under paragraph (e) of this section is not available.

(2) If lump sum payment for purchase would cause the beneficiary an undue financial hardship, the lump sum payment shall be deferred for up to 3 months. Interim rental payments shall be made during this period in accordance with paragraph (j) of this section.

(g) *Payment for rental charges.* (1) The carrier shall pay for durable medical equipment on the basis of reasonable rental charges, for the period the equipment is medically needed, if:

(i) Purchase of the equipment is less practical or more costly than the total reasonable rental charge for the period the beneficiary is expected to have a medical need for the equipment. However, payment may not be made on a rental basis for items listed in HCFA guidelines for purchase only (see paragraph (c)(2)(vi) of this section), except as indicated in paragraph (h)(4) of this section; or

(ii) The beneficiary continues to rent the equipment after notification from the carrier that payment should be made on the basis of lease-purchase or lump sum payment for purchase. However, the total rental payments for months after the month the notification was dated may not exceed the amount that would have been paid based on the reasonable purchase price of the equipment. If the beneficiary later purchases the equipment, the carrier shall deduct from the purchase payment the total reasonable rental charges paid for months after the month the notification was dated.

(2) If rental payments are made in accordance with paragraph (g)(1)(i) of this section, and purchase of the equipment is later warranted (for example, due to changes in the beneficiary's medical condition), the carrier shall make a new reasonable charge determination. In these instances, the rental payments that have already been made need not be deducted from the reasonable charge payable for the purchase, unless under the terms of the purchase agreement, those payments apply toward the purchase price. (Also see paragraph (k) of this section on waiver of coinsurance upon purchase of used equipment.)

(3) If a beneficiary purchases an item, but the carrier determines that payment should be made on the basis of rental charges, the carrier shall pay on a rental basis until the medical necessity for the equipment ends, or until the reasonable lump-sum purchase price is paid, whichever occurs first.

(h) *Interim payments for rental charges.* (1) Section 1833(f)(1) of the Social Security Act requires the Secretary to determine if purchase of durable medical equipment is less costly or more practical than rental, and if so, to make payment on a purchase basis, unless purchase would be inconsistent with the purposes of the Medicare program or would cause an undue financial hardship on the beneficiary.

(2) If the carrier determines that payment should be based on purchase, it shall make interim rental payments for a maximum of six months from the first month the equipment was rented through the month following the month in the date on the carrier's payment determination notice. The carrier may extend the six-month period for good cause, if, for example, the carrier determines that the beneficiary of the supplier is without fault in delaying the filing of the claim, or there was a delay in the carrier's processing of the claim.

(3) These interim rental payments are in addition to the purchase payment unless, under the terms of the purchase agreement, the rental payments apply toward the purchase price.

(4) The carrier may pay interim rental charges on an item listed in HCFA guidelines for lump sum purchase only, if—

(i) The carrier determines that the beneficiary has an undue financial hardship (see paragraph (j) of this section); or

(ii) The carrier determines in extraordinary cases that neither the supplier nor the beneficiary was aware that the item was listed in HCFA guidelines for purchase only.

(i) *Payment for interest and carrying charges.* Lump sum payments for purchase under this section may include reasonable interest and carrying charges when Medicare deductible and coinsurance amounts are paid in installments if:

(1) The interest or carrying charge is separately identified on the supplier's bill or on the Medicare request for payment;

(2) It is the usual and accepted practice in the locality for suppliers to make an extra charge;

(3) The practice of making an extra charge for installment payments applies to non-Medicare purchasers as well as to Medicare beneficiaries; and

(4) The additional amount charged does not exceed an applicable State or local government interest limit.

(j) *Undue financial hardships.* (1) The carrier shall consider the purchase of durable medical equipment an undue financial hardship on the beneficiary only if:

(i) The beneficiary states in writing that he cannot afford to pay the deductible or coinsurance amount to the supplier in a lump sum, he is unable to arrange with the supplier to pay these amounts in installments, and he is not currently a recipient of a local or State program, such as Medicaid, that could make these payments for him; and

(ii) The carrier determines that it is the supplier's business practice not to enter into installment payment arrangements with customers.

(2) If the carrier determines that payment should be made by lump sum, but has concluded that this would cause the beneficiary undue financial hardship, the carrier shall make a maximum of 3 months interim rental payments, in addition to those made under paragraph (h) of this section, to give the beneficiary time to resolve the hardship.

(i) If the beneficiary subsequently purchases the equipment from the supplier who originally furnished it, the carrier shall deduct these additional interim rental payments from the purchase payment, unless the item is not readily available from another supplier.

(ii) If the beneficiary subsequently purchases the equipment from a different supplier, the carrier may not deduct these additional interim rental payments from the purchase payment.

(k) *Waiver of coinsurance for purchase of used equipment.* (1) The carrier shall waive the 20 percent coinsurance that Medicare Part B beneficiaries are required to pay under § 410.152 of this chapter, but not the deductible requirements of § 410.160 of this chapter, for the purchase of used durable medical equipment if:

(i) The carrier determines that payment should be made by lease-purchase or lump sum payment for purchase, rather than by rental charges;

(ii) The actual charge is at least 25 percent less than the reasonable charge the carrier has set for comparable new equipment; and

(iii) The requirements of paragraph (k)(2) or (3) of this section are met.

(2) If used equipment is purchased from a commercial supplier, the supplier must give the beneficiary a signed and dated warranty that assured the following:

(i) The used equipment is in good working order and has no defects in workmanship or material.

(ii) The supplier pays for the costs of replacement of faculty parts (including labor, shipping, and handling costs) or replaces the item of equipment at no cost if—

(A) The equipment fails within one-half the period of time specified by the manufacturer's warranty for the same equipment when new; and

(B) The failure is one that is covered under that manufacturer's warranty.

(3) If used equipment is purchased from a private source rather than from a commercial supplier, the beneficiary must state that he is satisfied that the equipment is in good working order and that he believes it can be expected to give satisfactory service for its anticipated period of use.

(Secs. 1102 and 1833 (f), Social Security Act (42 U.S.C. 1302 and 1395l(f)))

[45 FR 44290, July 1, 1980, as amended at 51 FR 41351, Nov. 14, 1986; 52 FR 6152, Mar. 2, 1987]

§ 405.515 Reimbursement for clinical laboratory services billed by physicians.

This section implements section 1842(h) of the Social Security Act, which places a limitation on reimbursement for markups on clinical laboratory services billed by physicians. If a physician's bill, or a request for payment for a physician's services, includes a charge for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as follows (subject to the coinsurance and deductible provisions at §§ 410.152 and 410.160 of this chapter):

(a) If the bill or request for payment indicates that the test was personally performed or supervised either by the physician who submitted the bill (or for whose services the request for payment was made), or by another physician with whom that physician shares his or her practice, the payment will be based on the physician's reasonable charge for the test (as determined in accordance with § 405.502).

(b) If the bill or request for payment indicates that the test was performed by an outside laboratory, and identifies both the laboratory and the amount the laboratory charged, payment for the test will be based on the lower of—

(1) The laboratory's reasonable charge for the service (as determined in accordance with § 405.502), or

(2) The amount that the laboratory charged the physician for the service.

(c) If the bill or request for payment does not indicate that the conditions specified in paragraph (a) of this section were met, and does not identify both the laboratory and the amount the laboratory charged, payment will be based on the lowest charge at which the carrier estimates the test could have been secured from a laboratory serving the physician's locality. The carrier will estimate this lowest amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier's area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier's service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with § 405.511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.520 Reimbursement for services of interns, residents and supervising physicians; general.

(a) Under the health insurance program, almost all the aged have protection against hospital expenses, and the great majority also have protection against medical expenses. This health insurance coverage is intended to provide a substantial measure of freedom to beneficiaries in selecting hospitals and physicians of their choice. Whatever the choice, beneficiaries, as insured patients, are to be accorded the same status as other insured and paying patients in regard to the hospital and medical care they are provided.

(b) Many beneficiaries will choose to receive the care they need from hospitals with approved graduate medical education programs and from other institutions where services of interns and residents are provided. Many will receive care in these hospitals as patients of physicians who, in turn, will involve interns and residents in the care of their patients. The basis for reimbursement for such services by interns and residents is different from that applicable to such physicians' services.

§ 405.521 Services of attending physicians supervising interns and residents.

(a) Attending physicians' services rendered to beneficiaries in a teaching setting are covered under the supplementary medical insurance program and the payment for such services is on the basis of reasonable charges (see paragraphs (b) and (c) of this section). The costs to a hospital for teaching services furnished by a physician in connection with an approved graduate medical education program are allowable in accordance with the principles of reimbursement for provider costs (see paragraph (d) of this section).

(b) Payment on the basis of reasonable charges is applicable to the professional services rendered to a beneficiary by his attending physician where the attending physician provides personal and identifiable direction to interns or residents who are participating in the care of his patient. In the case of major surgical procedures and other complex and dangerous procedures or situations, such personal and identifiable direction must include supervision in person by the attending physician. A charge should be recognized under Part B for the services of an attending physician who involves residents and interns in the care of his patient only if his services to the patient are of the same character, in terms of the responsibilities to the patient that are assumed and fulfilled, as the services he renders to his other paying patients. The carrying out by the physician of these responsibilities would be demonstrated by such actions as: Reviewing the patient's history and physical examination and personally examining the patient within a reasonable period after admission; confirming or revising diagnosis; determining the course of treatment to be followed; assuring that any supervision needed by the interns and residents was furnished; and by making frequent reviews of the patient's progress.

(c) Charges for such services of the attending physician may be billed either directly by him or by the hospital under arrangements between the physician and the hospital. In either case, the amount payable under the program for such services may be determined in accordance with the same criteria for the determination of reasonable charges as are applicable to the services which the physician renders to his other patients (see §§ 405.501-405.508 of this Subpart E).

(d) (1) It is recognized that there will necessarily be situations where a patient will receive medical services in the teaching setting for which payment on the basis of reasonable charges will not be applicable. For example, there will be instances where it will neither be necessary from the standpoint of the medical needs of the patient nor appropriate from the standpoint of the continuing development of the residents' competence for there to be an attending physician who carries out the responsibilities referred to in paragraph (b) of this section. Whether or not a physician makes a charge recognized under the supplementary medical insurance program for services to patients which involve the participation of residents or interns, the hospital can receive reimbursement on a cost basis for an appropriate share of the compensation it pays its residents and interns. If the teaching program is an approved educational activity of the hospital, reimbursement will also be available on a cost basis to the hospital for an appropriate share of the compensation it pays to physicians for teaching services (as opposed to professional services which contribute to the diagnosis or treatment of the patient) and for other costs of educational programs conducted by the hospital. These costs are allowable in accordance with the principles of reimbursement for provider costs (see § 413.85 of this chapter).

(2) For cost-reporting periods beginning after June 30, 1973, and before July 1, 1976, a hospital with an approved teaching program (see § 405.522(a)) may elect to receive reimbursement on a reasonable cost basis for the direct medical and surgical services of its physicians in lieu of any payment on the basis of reasonable charges which might otherwise be payable for such services. A hospital

may make this election to receive cost reimbursement only where all physicians who render services in the hospital which are covered under the health insurance program agree not to bill charges for such services (or where all the physicians are employees of the hospital and as a condition of employment they are precluded from billing for such services). Where the requirements of this paragraph (d)(2) are satisfied by a hospital, the reimbursement provisions of § 405.465 are applicable.

(3) Where payments for services of physicians in teaching hospitals rendered after June 30, 1973, and before December 31, 1973, would be improper by virtue of section 15(a) of Pub. L. 93-233 (87 Stat. 965), such payments are deemed proper even though they may not meet the requirements which are based on section 15(a) of Pub. L. 93-233, if they are appropriately made under the provisions of section 227 of Pub. L. 92-603 (86 Stat. 1404).

(e) Nothing in the foregoing restricts the disposition of payments for services received either from the health insurance program or from beneficiaries, in accordance with agreements between hospital and physicians.

[32 FR 12599, Aug. 31, 1967, as amended at 40 FR 33443, Aug. 8, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 34792, Sept. 30, 1986]

§ 405.522 Interns' and residents' services in approved teaching programs.

(a) Title XVIII of the Act gives recognition to hospital teaching programs which are duly approved in their respective fields by the Council on Medical Education of the American Medical Association, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, by the Council on Dental Education of the American Dental Association, or, for provider cost reporting periods beginning after December 31, 1972, by the Council on Podiatry Education of the American Podiatry Association.

(b) Services of interns and residents in such approved programs are explicitly excluded from the definition of "physicians' services" and are covered as hospital services. This exclusion applies whether or not the intern or resident may be authorized to practice as a physician under the laws of the State in which he performs his services. In accordance with the basis for payment under the health insurance program for services provided by participating hospitals, the cost of the services of interns and residents is reimbursable to the hospital, specifically as a component of allowable costs defined by the principles of reimbursement for provider costs set forth in Part 413 of this chapter. Under the principles discussed in Part 413 of this chapter, an appropriate share of the provider's total allowable costs is reimbursable under the health insurance program. (For purposes of including services of interns and residents as an element of allowable cost in accordance with these principles, recording and reporting by the hospital of the specific services rendered to individual beneficiaries is not necessary.)

(c) Conversely, services of interns and residents are not reimbursable under the health insurance program on the basis which applies to physicians' services, i.e., reasonable charges (see §§ 405.501-405.508). This distinction with respect to the basis for the health insurance program reimbursement applies to services of interns and residents whether covered by the hospital insurance program or the supplementary medical insurance program. Outpatient services which are provided by a hospital, including intern and resident services where involved, are reimbursed to the hospital under the supplementary medical insurance program to the extent of 80 percent of the cost of the services rendered to beneficiaries after recognition of the deductible amount (see § 410.152 of this chapter). The beneficiary will incur the expense of the deductible and coinsurance amounts as determined on the basis of the hospital's charges to the beneficiary. Hospital charges may include a charge for the services of interns and residents as a specific item, or these services may be included in the general charges to the beneficiary made by the hospital for the covered services it provides.

[39 FR 32328, Sept. 6, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 34792, Sept. 30, 1986; 51 FR 41351, Nov. 14, 1986]

§ 405.523 Interns' and residents' services not in approved teaching programs.

(a) The services of a hospital resident or intern who is not under an approved teaching program in the hospital are reimbursable to the hospital on a cost basis under the supplementary medical insurance program. For purposes of this section, such services shall be deemed to include services of a physician employed by the hospital who is authorized to practice only in a hospital setting. Even where such services are rendered to inpatients, the cost of the services is not an allowable cost under the hospital insurance program but is allowable under the supplementary medical insurance program.

(b) In this connection reimbursement under the health insurance program for services discussed in paragraph (a) of this section will be to the hospital in an amount of 80 percent of the cost of services rendered to the beneficiaries after recognition of the deductible. The beneficiary will incur the expense of the deductible and coinsurance amounts as determined on the basis of the hospital's charges to the beneficiary for its services that are covered under the supplementary medical insurance program.

§ 405.524 Interns' and residents' services outside the hospital.

(a) Under the hospital insurance program, the allowable costs on which reimbursement to a participating extended care facility for covered services is based may include the cost of services of an intern or resident who is under an approved teaching program in a hospital with which the facility has a transfer agreement (see § 405.1133) which provides, in part, for the transfer of patients and the interchange of medical records. Likewise, a participating home health agency may be reimbursed under the hospital insurance program for the cost of the services of an intern or resident who is under an approved teaching program of a hospital with which the home health agency is affiliated or under common control where these services are furnished as part of the posthospital home health visits for a Medicare beneficiary.

(b) Medical services of a resident or intern of a hospital which are furnished by a provider of services are reimbursed under the supplementary medical insurance program on an 80 percent of allowable cost basis if reimbursement is not provided under the hospital insurance program.

§ 405.525 Basis of reimbursement to providers under the health insurance program for services of interns and residents.[1]

Status of patient	Status of intern or resident [1]	Reimbursement provided under [2]	Basis of payment [3]
Hospital inpatient	Under approved program	Part A	Cost.
	Other	Part B	80 percent of cost.
Hospital outpatient	Under approved program	do.	Do.
	Other	do.	Do.
Skilled nursing facility patient.	Under approved program of a hospital with which facility has a transfer agreement.	Part A	Cost.
	Other	Part B	80 percent of cost.
Home health plan patient	Posthospital services furnished under approved program of hospital with which the home health agency is affiliated or under common control.	Part A	Cost.
	Other	Part B	Do.

[1] An "approved program" means a program approved by the Council on Medical Education of the American Medical Association, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, or by the Council on Dental Education of the American Dental Association; or with respect to providers' accounting periods beginning after Dec. 31, 1972, by the Council on Podiatry Education of the American Podiatry Association. "Other" interns and

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[1] See sections 1814(d) and 1835(b) of the Social Security Act concerning reimbursement for emergency services rendered by hospitals which are not providers under the health insurance program.

residents include, in addition to interns and residents-in-training, a physician employed by the hospital who is authorized to practice only in the hospital setting.

[2] "Part A" refers to the hospital insurance program and "part B" refers to the supplementary medical insurance program.

[3] The term "cost" refers to reimbursement on a cost basis in accordance with the principles in Part 413 of this chapter.

[39 FR 32329, Sept. 6, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 34792, Sept. 30, 1986]

§ 405.541 Criteria for determination of reasonable charges for items and services furnished by nonprovider ESRD facilities before August 1, 1983.

(a) *Determination of a facility's customary charge.* (1) This section applies to payment for items and services furnished by a nonprovider (independent) ESRD facility after June 30, 1973 and before August 1, 1983. (Payment for items or services furnished on or after that date will be made under §§ 405.544 and 413.170 of this chapter.) This section applies in place of the reasonable charge criteria in § 405.503.

(2) The customary charge of a facility for outpatient maintenance dialysis is determined based on the weighted average of reimbursements from all parties made to the facility for dialysis treatments furnished during the 12-month period preceding July 1, 1973.

(3) If a customary charge cannot be determined in this basis because the facility was not in operation during the 12-month period preceding July 1, 1973, the reimbursable amount will be determined considering the facility's proposed schedule of charges and the charges of comparable facilities in the area.

(4) Whichever method is used to determine a facility's customary charge, the amount payable is subject to the limitation described in paragraphs (b) and (c) of this section.

(b) *Determination of reimbursable amount for maintenance dialysis.* Subject to the deductible and coinsurance, the reimbursable amount to a nonprovider renal dialysis facility for a maintenance dialysis treatment shall be the lower of the customary charge as derived in paragraph (a) of this section, or an administratively determined "screen," i.e., an amount derived from available data that may be periodically revised to reflect changes in the data, and used for identifying costs or charges which appear atypically high and therefore require documentation to justify their reasonableness. In determining the screen amounts, costs or charges of facilities which include laboratory services and/or physicians' supervisory services are taken into account. A separate screen is determined for nonprovider facilities which furnish extended peritoneal dialysis treatments (i.e., at least 30 hours in duration). A facility may request an equity adjustment in the reimbursable amount in accordance with paragraphs (e) and (f)(2) of this section. See also paragraph (d) of this section regarding the effect on the amount payable where the physician elects Physician Reimbursement Method No. 2.

(c) *Determination of reimbursable amount for self dialysis training.* Subject to the deductible and coinsurance, the amount payable for a self-dialysis training session to a nonprovider facility shall be the lower of the customary charge described in paragraph (a) of this section, or the screen amount for a self-dialysis training session. In determining the screen amounts, costs or charges of facilities which include laboratory services and/or physicians' supervisory services are taken into account. For services furnished after June 30, 1974, reimbursement for physicians' services for self-dialysis training shall be made directly to the physicians in accordance with § 405.542(c) rather than being included in the facility's training session payment.

(d) *Reimbursable amount when physicians elect Physician Reimbursement Method No. 2.* Where the physicians rendering services to patients in a facility elect Physician Reimbursement Method No. 2, described in § 405.542(b) the screen amounts described in paragraphs (b) and (c) of this section will be reduced by a standard amount determined from available data or by the payment that was being made through the facility for the physician's supervisory services rendered to maintenance dialysis and self-dialysis training patients, whichever reduction yields the lesser rate. Where the facility was reimbursed at a rate below the screen amounts described in paragraphs (b) and (c) of this section, this rate should be reduced either by an amount equivalent to the portion that was previously being paid for physicians' supervisory services described in § 405.542(a)(1) or to the screen amount adjusted for the standard amount as in the foregoing sentence, whichever reduction yields the lesser rate.

(e) *Adjustment of reimbursable amount in case of unusual hardship.* Before August 1, 1983, a facility which can demonstrate unusual hardship because of the amount of payment made under the ESRD program may submit documentation of its costs and request a determination with respect to an equity adjustment in the payment. For rules governing exceptions to payment rates effective after that date, see § 413.170(f) of this chapter.

(f) *Required cost data.* (1) Nonprovider ESRD facilities are required to furnish adequate cost information, in accordance with section 1833(e) of the Act (42 U.S.C. 1395(e)). This information will be used for the following purposes:

(i) Determination of rates of reimbursement for outpatient maintenance dialysis treatments and other reasonable and medically necessary services furnished in connection with these treatments.

(ii) Justification of requests made for adjustments in reimbursement rates under paragraph (e) of this section.

(iii) Accumulation of data for overall program evaluation.

(2) The cost information required under paragraph (f)(1) of this section shall be furnished by the nonprovider facilities in accordance with the cost reporting, recordkeeping, and audit requirements set forth in § 413.20 of this chapter.

(3) This requirement applies to all cost reporting periods ending before August 1, 1983. For cost reporting rules that apply to reporting periods ending on or after that date, see § 413.174 of this chapter.

[42 FR 65178, Dec. 30, 1977, as amended at 48 FR 21281, May 11, 1983; 51 FR 34792, Sept. 30, 1986]

§ 405.542 Criteria for determination of reasonable charges for physicians' services rendered to renal dialysis patients.

(a) *Principle.* Physicians' services to renal dialysis patients are reimbursable if the services are otherwise covered by the Medicare program and if they are reasonable and medically necessary. Physicians' services furnished between July 1, 1973 and July 31, 1983 may be reimbursed under either the "Initial Physician Reimbursement Method" described in paragraph (b) of this section or, if the physician so elects, under the "Physician Monthly Capitation Payment Method" described in paragraph (c) of this section. Physicians' services furnished on or after August 1, 1983 are reimbursable only under the monthly capitation method as described in paragraph (c) of this section. This section applies to all physicians' services furnished to outpatient maintenance dialysis patients in either a nonprovider (independent) or a provider (hospital-based) ESRD facility, or to patients dialyzing at home.

(b) *Initial physician reimbursement method, effective for services furnished before August 1, 1983.* Under this method, supervisory services, as defined in paragraph (b)(1) of this section, provided by physicians to outpatient maintenance dialysis patients are reimbursable to the facility by the intermediary as a facility service part of the dialysis session if the physician has actually furnished the service. Physicians' administrative services are considered to be facility costs (see paragraph (b)(2) of this section) included in the rates of payment for dialysis treatments and are reimbursable to the facility. Nonroutine services rendered to patients during and related to the dialysis procedure (see paragraph (b)(3)(i) of this section) and services which must be rendered at a time other than during the dialysis procedure (see paragraph (b)(3)(ii) of this section) are reimbursable to the physician (or to the beneficiary) by the carrier in accordance with the reasonable charge criteria set forth in § 405.502 (a) through (d). Physicians' services rendered to hospital inpatients who were not admitted solely to receive maintenance dialysis and to patients who are self-dialyzing at home are also reimbursable under these reasonable charge criteria.

(1) *Supervisory services defined.* Supervisory services for patients who are receiving maintenance dialysis or self dialysis training in a facility are those physicians' services which are related to the care of the patient and the need for medical management over the period of time the patient is on maintenance or training dialysis. They are non-episodic services which are furnished during the dialysis session; they reflect the facility's responsibility to provide services under the general supervision of a physician. They include all patient care services not specifically defined as nonroutine in paragraph (b)(3)(i) of this section. Supervisory services include, at least all of the following when medically appropriate:

(i) Being available to patients and to staff for consultation on the care of the patients;

(ii) Overseeing the performance of dialysis on individual patients, including but not limited to review of laboratory tests and adjustments of dialysis procedures;

(iii) Monitoring the patient's medical status and vital signs, including needed adjustments in medications;

(iv) Determining the need for supplies and medications and authorizing them;

(v) Reviewing dietary issues and modifying dietary control as needed;

(vi) Evaluating the appropriateness of the patient's proposed treatment modality;

(vii) Reviewing psychosocial issues;

(viii) Making pre- and post-dialysis examinations where medically appropriate; and

(ix) Repeated insertions of a catheter for patients on maintenance peritoneal dialysis who are not provided an indwelling catheter.

(2) *Administrative services defined.* The administrative services that are rendered by physicians and that are directly related to the support of the facility are a part of the facility's cost or charge for dialysis. These services are differentiated from supervisory services and other physicians' services related to patient care because they are not related directly to the patient's care, but are of benefit to all of the patients as a whole as well as to the facility. Examples of such services include staff training, participating in the management of the facility, advising on procurement of facility supplies, supervising staff for other than direct patient care services, and staff conferences.

(3) *Services not included in supervisory or administrative services.* Physician services not considered as supervisory services (or administrative services) are:

(i) Services rendered during dialysis which are nonroutine i.e., declotting of shunts, needle insertions into fistulae, supervision of blood transfusions, care during immediately life-threatening complications related to the dialysis procedure, and care of nonrenal conditions; and (ii) services which must be rendered at a time other than during the dialysis procedure, e.g., monthly and semi-annual examinations to review health status and treatment.

(c) *Physician monthly capitation payment method.* All physician services, other than those specified in paragraph (c)(1) of this section, rendered to each outpatient maintenance dialysis patient (regardless of the patient's mode of or setting for dialysis) will be reimbursed by the carrier on a monthly capitation basis. Payment of the monthly amount, subject to the deductible and coinsurance, for all such services provided for that month is made by the carrier either to the physician, if the physician accepts assignment, or to the patient, if the physician does not accept assignment. This reimbursement method recognizes the need of patients on maintenance renal dialysis for continuing medical management over relatively long periods of time, and is responsive to physicians' charging patterns in their localities. The physician must provide to a patient all physician services not listed in paragraph (c)(1) of this section that are required by the patient in a month to qualify for this reimbursement in that month.

(1) *Services not included in monthly payment.* Physician services not cov-

ered by the monthly payment, which may be reimbursed in accordance with the usual reasonable charge rules, are limited to:

(i) Declotting of shunts.

(ii) Covered physicians' services furnished by another physician during periods when the patient or his attending physician is not available for outpatient services as set out in paragraph (c)(3) of this section.

(iii) Needed physician services which are rendered either by the physician providing renal care or by another physician and which are beyond those related to the treatment of the patient's renal condition and which are not incidental to services during a dialysis session or office visit necessitated by the renal conditions. The physician should provide documentation that the illness is not related to the renal condition and that added visits are required. The carrier's medical staff, acting also on the basis of medical consultation obtained by the carrier as may be appropriate, determines whether additional reimbursement is warranted for treatment of the unrelated illness.

(iv) Covered physician services furnished to hospital inpatients by a physician who elects not to continue the capitation payment method through the period of the inpatient stay.

(2) *Reduction of monthly payment.* The monthly payment amount is reduced in proportion to the number of days the patient is: hospitalized and the physician elects to bill separately for services furnished during hospitalization; or not attended by the physician or his or her substitute for any reason, including when the physician is not available to provide patient care or when the patient is not available to receive such care.

(3) *Determination of monthly payment amount.* The factors used in determining the monthly payment amounts will be related to program experience and to the charging practices of comparable physicians for comparable services. The factors will be reevaluated periodically on the basis of program experience and may be adjusted as necessary to reflect changes in these charging practices and modes of furnishing services and to assure fairness. Revisions to the monthly amounts will be published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

(d) *Physician reimbursement for self-dialysis and home dialysis training.* Reimbursement for physicians' services rendered to dialysis patients undergoing self-dialysis and home dialysis training will be limited to a flat amount, to be determined from program experience—and reviewed periodically—for each patient under the physician's supervision during the training course, subject to the deductible and coinsurance provisions. Payment will be made upon completion of the training course, and will be in addition to any amounts payable under either of the reimbursement methods, described in paragraphs (b) and (c) of this section, for physicians' services rendered to a renal dialysis patient. Where the training course is not completed, e.g., the patient can no longer be trained, payment will be proportionate to the time spent in training. All those physicians' services determined to be required to create the capacity for self-dialysis and home dialysis are covered by this payment.

[48 FR 21281, May 11, 1983]

§ 405.543 Criteria for determination of reasonable charges for physicians renal transplantation services.

(a) *Payment for the period July 1, 1973 through April 14, 1975.* For the period July 1, 1973 through April 14, 1975, the reimbursable amount for physicians' services in connection with a renal transplantation, other than recipient nephrectomies including pre- and post-operative care for 180 days, was not to exceed $900, subject to the deductible and coinsurance. Additional payments in amounts established on the basis of program experience were allowed for other surgical procedures performed concurrently with the transplant operation.

(b) *Payment for period after April 14, 1975.* Based on a review of charge experience for renal transplantation services during the initial year of the ESRD program, these criteria were revised effective April 15, 1975. Beginning after April 14, 1975, comprehensive payments are made, subject to the deductible and the coinsurance, for all the surgeon's services in connection with a renal transplantation, including the usual pre- and post-operative surgical care, and for immuno-suppressant therapy, when supervised by the attending transplant surgeon, for a period of 60 days. Additional sums in amounts established on the basis of program experience, may be included in the comprehensive payment for other surgery performed concurrently with the transplant operation. The comprehensive payments to be made may not be based on amounts that exceed either the actual charges made for the transplantation services, or amounts the carriers derive from overall national payment levels established under the ESRD program and adjusted to give effect to variations in physicians' charges throughout the nation. (These adjusted amounts are the maximum allowances in a carrier's service area for renal transplantation surgery and related services by surgeons.) The maximum allowances, computed under these instructions, will be revised July 1, 1977, and at the beginning of each 12-month fee screen year thereafter to the extent permitted by the lesser of: Changes in the economic index as described in § 405.504(a)(3)(i), or percentage changes, from one year to the succeeding year, in the weighted average of the servicing carrier's prevailing charges (before adjustment by the economic index) or for a unilateral nephrectomy (or for another medical or surgical service that may be designated by the Secretary for this purpose). Payments for covered medical services provided to the transplant recipient by other specialists, as well as for services by the transplant surgeon after the 60-day period covered by the comprehensive payment, shall be made under the reasonable charge criteria set forth in § 405.502 (a) through (d). The payments for physicians' services in connection with renal transplantations will be changed on the basis of program experience and the expected advances in the medical art for this operation.

[42 FR 65180, Dec. 30, 1977]

§ 405.544 Payment for home dialysis equipment, supplies, and support services

(a) *Equipment and supplies.* (1) Equipment and supplies furnished to patients before August 1, 1983:

(i) Are reimbursable on a reasonable cost basis in accordance with Part 413 of this chapter if they are furnished by an ESRD facility that does not have an agreement with HCFA under § 405.690 (for purchase, installation, maintenance, and reconditioning of home dialysis equipment) or § 405.691 (for target rate reimbursement for home dialysis services); or

(ii) Are reimbursable on a reasonable charge basis in accordance with § 405.502 (a) through (d) if they are not furnished by or through an ESRD facility.

(2) Equipment and supplies furnished to patients on or after August 1, 1983:

(i) Are reimbursable only under the prospective payment rates established under § 413.170 of this chapter, except as provided in paragraphs (a)(2)(ii) or (a)(2)(iii) of this section;

(ii) Are reimbursable to a party other than an approved ESRD facility on a reasonable charge basis in accordance with § 405.502 (a) through (d) if the home dialysis patient elects, in accordance with procedures established by HFCA, to obtain his or her home dialysis equipment, supplies, or both from a supplier other than an approved ESRD facility. If the home dialysis patient elects to obtain either equipment or supplies, but not both, from a supplier other than an approved ESRD facility, then the one obtained through the approved ESRD facility is reimbursable on a reasonable cost basis in accordance with Part 413 of this chapter; or

(iii) If equipment is furnished under an agreement under § 405.690 (for purchase, installation, maintenance, and reconditioning of home dialysis equipment), the equipment and related services are reimbursable on a reasonable cost basis under § 405.438[1]. In this case supplies are reimbursable on the basis of prorated prospective payment rates established under § 413.170 of this chapter, unless paragraph (a)(2)(ii) of this section applies.

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[1] Section 405.438 was removed at 51 FR 34792, Sept. 30, 1986.

(b) *Support services.* (1) Support services furnished to patients before August 1, 1983:

(i) Are reimbursable on a reasonable cost basis in accordance with Part 413 of this chapter if they are furnished by a hospital-based ESRD facility that does not have an agreement with HCFA under § 405.691 (for target rate reimbursement for home dialysis services); or

(ii) Are reimbursable on a reasonable charge basis in accordance with § 405.502 (a) through (d) if they are furnished by an independent ESRD facility that does not have an agreement with HCFA under § 405.691 (for target rate reimbursement for home dialysis services).

(2) Support services furnished to patients on or after August 1, 1983:

(i) Are reimbursable only under the prospective payment rates established under § 413.170 of this chapter, except as provided in paragraph (b)(2) (ii) or (iii) of this section;

(ii) If the patient elects to obtain his or her home dialysis equipment, supplies, or both as described in paragraph (a)(2)(ii) of this section, support services furnished to the patient by a hospital-based ESRD facility are reimbursable on a reasonable cost basis in accordance with Part 413 of this chapter, and support services furnished by an independent ESRD facility are reimbursable on a reasonable charge basis in accordance with § 405.502 (a) through (d); or

(iii) If equipment is reimbursable under paragraph (a)(2)(iii) of this section, then support services are reimbursable on the basis of prorated prospective payment rates established under § 413.170 of this chapter unless paragraph (b)(2)(ii) of this section applies.

[48 FR 21282, May 11, 1983, as amended at 51 FR 34792, Sept. 30, 1986]

SERVICES OF PHYSICIANS IN PROVIDERS

§ 405.550 Conditions for payment of charges for physician services to patients in providers: General provisions.

(a) *Scope.* This section implements section 1887(a)(1) of the Act by providing general conditions that must be met in order for services furnished by physicians in providers to be paid for on the basis of reasonable charges under this subpart. Section 405.551 sets forth general requirements for determining the amounts of payment for services that meet the conditions of this section. Sections 405.552 through 405.557 set forth additional conditions for payment and rules for determining reasonable charges for physician services in the specialities of anesthesiology, radiology, and pathology (laboratory services).

(b) *Conditions for payment for services of physicians to provider patients.* The carrier will pay for services of physicians to patients of providers on a reasonable charge basis only if the following requirements are met:

(1) The services are personally furnished for an individual patient by a physician;

(2) The services contribute directly to the diagnosis or treatment of an individual patient;

(3) The services ordinarily require performance by a physician; and

(4) In the case of anesthesiology, radiology, or laboratory services, the additional requirements in §§ 405.552, 405.554, or 405.556 must be met.

(c) *Services of physicians to providers.* If a physician furnishes services in a provider that do not meet the requirements in paragraph (b) of this section but are related to the provision of patient care by the provider, the intermediary will pay for those services, if otherwise covered, under the rules in §§ 405.480 and 405.481 on reasonable cost payment for physician services to providers.

(d) *Effect of billing charges for physician services to a provider* (1) For services performed by a physician that may be reimbursed under the reasonable cost rules in § 405.480 or § 405.481 or would be paid under those rules except for the prospective payment rules in Part 412 of this chapter, neither provider nor physician may seek charge payment from the carrier, beneficiary, or another insurer.

(2) The carrier will not pay on a reasonable charge basis for services furnished by a physician to an individual patient that do not meet the applicable conditions in §§ 405.552, 405.554, and 405.556.

(3) If the physician, the provider, or another entity bills the carrier or the beneficiary for physician services to the provider, as described in section § 405.480(a), the provider in which and to which the services were furnished may be considered to have violated its provider participation agreement, and that agreement may be terminated. See Part 489 of this chapter for rules governing provider agreements.

(e) *Effect of physician's assumption of operating costs.* If a physician or other entity enters into an agreement (such as a lease or concession) with a provider, under which the physician (or entity) assumes some or all of the operating costs of the provider department in which the physician furnishes physician services in the provider, the following rules apply:

(1) The carrier will make reasonable charge payments only for a physician's services to an individual patient.

(2) To the extent the provider incurs a cost reimbursable on a reasonable cost basis under Part 413 of this chapter, the intermediary will pay the provider on a reasonable cost basis for the costs associated with producing these services, including overhead, supply, and equipment costs, and services furnished by nonphysician personnel.

(3) The physician (or other entity) will be treated as related to the provider within the meaning of § 413.17 of this chapter.

(4) The physician (or other entity) must make its books and records available to the provider and the intermediary as necessary to verify the nature and extent of the costs of the services furnished by the physician (or other entity).

[48 FR 8937, Mar. 2, 1983, as amended at 48 FR 39830, Sept. 1, 1983; 48 FR 48468, Oct. 19, 1983; 51 FR 34792, Sept. 30, 1986]

§ 405.551 Reasonable charges for physician services in providers: General provisions.

(a) *Scope.* The carrier determines reasonable charges for physican services to patients in providers in accordance with the general rules governing reasonable charge payment in §§ 405.501 through 405.508, except as provided in the following paragraphs of this sections.

(b) *Application in certain settings*—(1) *Teaching hospitals.* In determining the amount of payment for physician services to individual patients in a teaching hospital, the carrier applies the rules in § 405.521 in addition to those in this section.

(2) *Hospital-based ESRD facilities.* In determining the amount of payment for physician services to individual patients furnished in a hospital-based end-stage renal disease (ESRD) facility certified under Subpart U of this Part, the carrier will apply the rules in § 405.542 instead of those in this section.

(c) *Customary and prevailing charges for physician services in provider settings.* (1) The carrier will calculate customary and prevailing charges for physician services furnished to individual patients in providers, in accordance with the general rules in §§ 405.501 through 405.508, separating, when appropriate, charges for physician services furnished in provider-based practices and physician services furnished in office-based practices.

(2) The carrier will apply the appropriate prevailing charge screens in determining reasonable charges for physician services, considering the setting.

(d) *Compensation-related charges.* (1) In developing customary charges for physician services furnished in providers by physicians compensated by the provider or a related organization for those services, the carrier will establish a schedule of charges related to that part of the physician's compensation that is allocated to physician services to individual patients under § 405.481. (In a teaching hospital, compensation-related charges may be based on payments made, to the physician for services furnished to patients in the hospital, by a political subdivision, university, or medical school, irrespectively of whether it is a related organization.) The carrier generally will use the compensation paid to the physician during the hospital's most recently ended cost reporting period for this purpose. If this information is unavailable from the intermediary, the intermediary will make a reasonable estimate of a fair compensation amount based on what is paid for similar services in another hospital.

(2) The carrier develops compensation-related charges on an item-by-item basis, considering the frequency with which the various services are furnished, and the relative values assigned to each service in a relative value study.

(3) The intermediary may pay the provider, for physicians' services to an individual patient, on the basis of a single per diem, per visit, or other time-related rate, if the provider, or the particular department in which the services are furnished, has a uniform all-inclusive rate for services to patients.

(e) *Change of agreements.* For services furnished on or after January 1, 1987, if a physician who has been compensated by or through a provider (or other entity) for physician services to individual patients ends his or her compensation agreement and instead bills all patients, or their insurers, directly for his or her services, the carrier determines the physician's customary charge for a service based on the 50th percentile of the weighted customary charges used to establish the prevailing charge for the service until the carrier has accumulated charge data from at least three months of the 12 month period of July 1 through June 30 preceding the January 1 annual reasonable charge update. However, if a physician terminates a direct billing arrangement and enters into a compensation agreement with a provider, the carrier determines compensation-related customary charges in accordance with paragraph (d) of this section except that during the first year, the total payments made on the basis of the compensation-related charges may not exceed what total payment would have been under the physician's former direct billing practice.

(f) *Rules for certain specialties.* In determining the amount of payment for anesthesiology or radiology services furnished by a physician to an individual patient, the carrier will apply the rules in this section and in §§ 405.553 and 405.555 in addition to the general rules governing reasonable charges at §§ 405.501 through 405.508.

[48 FR 8937, Mar. 2, 1983, as amended at 52 FR 6152, Mar. 2, 1987]

§ 405.552 Conditions for payment of charges: Anesthesiology services.

(a) *Services furnished directly or concurrently.* The carrier will reimburse a physician for anesthesiology services furnished to patients in a provider on a reasonable charge basis only if the services meet the conditions for reasonable charge payment in § 405.550(b) and the following additional conditions are met:

(1) For each patient, the physician—

(i) Performs a pre-anesthetic examination and evaluation;

(ii) Prescribes the anesthesia plan;

(iii) Personally participates in the most demanding procedures in the anesthesia plan, including induction and emergence;

(iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual;

(v) Monitors the course of anesthesia administration at frequent intervals;

(vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and

(vii) Provides indicated postanesthesia care.

(2) The physician either performs the procedure directly, without the assistance of an anesthetist, or directs no more than four anesthesia procedures concurrently, and does not perform any other services while he or she is directing the concurrent procedures.

(b) *Supervision of more than four procedures concurrently.* If the physician is involved in furnishing more than four procedures concurrently, or is performing other services while directing the concurrent procedures, the concurrent anesthesia services are physician services to the provider in which the procedures are performed. In such cases, the physician is not required to meet the criteria of paragraphs (a)(1)(iii) and (vii) of this section personally, but must ensure that a qualified individual performs any procedure in which the physician does not personally participate. In these cases, the intermediary will pay for the services under the rules in §§ 405.480 and 405.481 on reasonable cost payment for physician services to providers.

[48 FR 8938, Mar. 2, 1983, as amended at 48 FR 39830, Sept. 1, 1983]

§ 405.553 Reasonable charges for anesthesiology services.

(a) *General rule.* In determining reasonable charge payment for anesthesiology services that meet the conditions in § 405.552(a), the carrier will follow the rules in paragraph (b) or (c) of this section.

(b) *Services furnished by the anesthesiologist or by an anesthetist employed by the anesthesiologist.* (1)(i) The provisions of this paragraph apply to anesthesia services furnished by an anesthesiologist without the assistance of an anesthetist or to anesthesia services furnished to hospital outpatients or SNF or CORF patients by an anesthetist who is employed by an anesthesiologist.

(ii) Except as provided in paragraph (b)(4) of this section, anesthesia services furnished to a hospital inpatient by an anesthetist under the medical direction of an anesthesiologist will be paid for in accordance with paragraph (c) of this section.

(iii) If the anesthetist who administers anesthesia under the direction of the anesthesiologist is employed by the anesthesiologist, the carrier will determine the amount of payment for the services under the reasonable charge rules for physician services in providers in § 405.551 and the general reasonable charge rules in §§ 405.501 through 405.508.

(2) In determining reasonable charges for these anesthesia services, the carrier will allow for no more than one time unit for each 15 minute interval, or fraction thereof, beginning from the time the physician or anesthetist begins to prepare the patient for induction of anesthesia, and ending when the patient may be safely placed under post-operative supervision and the physician or anesthetist is no longer in personal attendance.

(3) If a physician constructs his or her charges using time units of other than 15 minutes, the carrier will adjust the customary and prevailing charge screens to ensure that in a one-hour period the value of four 15-minute intervals will not be less than would have been allowed if the entire hour had consisted of intervals of another length, such as five 12-minute intervals or six 10 minute intervals.

(4) The provisions of paragraph (b)(1)(ii) of this section do not apply to inpatient hospital services furnished by an anesthetist employed by a physician if the services are furnished during cost reporting periods beginning on or after October 1, 1984 through any part of a cost reporting period occurring before January 1, 1989.

(c) *Anesthetist not employed by anesthesiologist.* If the anesthetist who administers anesthesia under the direction of the anesthesiologist is not employed by the anesthesiologist, the carrier will determine reasonable charges for the services by allowing no more than one time unit for each 30 minute interval, or fraction thereof, beginning from the time the anesthetist begins to prepare the patient for induction of anesthesia, and ending when the patient may be safely placed under post-operative supervision and the anesthetist is no longer in personal attendance.

[48 FR 8938, Mar. 2, 1983, as amended at 48 FR 39830, Sept. 1, 1983; 49 FR 34763, Aug. 31, 1984; 52 FR 33057, Sept. 1, 1987]

§ 405.554 Conditions for payment of charges: Radiology services.

(a) *Services to patients.* The carrier will reimburse radiology services furnished by a physician to an individual patient on a reasonable charge basis only if the services meet the conditions for reasonable charge payment in § 405.550(b) and are identifiable, direct, and discrete diagnostic or therapeutic services to an individual patient, such as interpretation of X-ray plates, angiograms, myelograms, pyelograms, or ultrasound procedures.

(b) *Services to providers.* The carrier will not pay on a reasonable charge basis for physician services to the provider (for example, administrative or supervisory services) or for provider services needed to produce the X-ray films or other items that are interpreted by the radiologist. However, allowable costs for such services will be paid to the provider by the intermediary. (See § 405.480 for provider costs, and § 405.550(e)(2) for costs borne by a physician, such as under a lease or concession agreement.)

[48 FR 8939, Mar. 2, 1983, as amended at 48 FR 39831, Sept. 1, 1983; 48 FR 48468, Oct. 19, 1983]

§ 405.555 Reasonable charges for radiology services.

(a) *General rule.* In determining payment for radiology services that meet the conditions for payment of charges in § 405.554, the carrier will follow the rules in paragraph (b) or (c) of this section.

(b) *Services not furnished in providers.* If the services are furnished in a radiologist's office, a freestanding radiology clinic, or any other setting that is not part of a provider, the carrier will determine the amount of payment for the services under the general reasonable charge rules in §§ 405.501 through 405.508.

(c) *Services furnished in providers.* If the services are furnished in a hospital radiology department or any other setting that is part of a provider, the following rules apply:

(1) The carrier will determine the amount of payment under the reasonable charge rules for physician services in providers in § 405.551 and the general reasonable charge rules in §§ 405.501 through 405.508.

(2) The reasonable charge for a physician's radiology service furnished to a hospital inpatient or furnished in a provider to a provider patient may not exceed 40 percent of the prevailing charge for a similar service furnished in a nonprovider setting.

[48 FR 8939, Mar. 2, 1983, as amended at 48 FR 39831, Sept. 1, 1983]

§ 405.556 Conditions for payment of charges: Physician laboratory services.

(a) *Physician laboratory services.* The carrier will reimburse laboratory services furnished by a physician to an individual patient on a reasonable charge basis only if the services meet the conditions for reasonable charge payment in § 405.550(b) and are—

(1) Anatomical pathology services;

(2) Consultative pathology services that meet the requirements in paragraph (b) of this section; or

(3) Services performed by a physician in personal administration of test devices, isotopes, or other materials to an individual patient.

(b) *Consultative pathology services.* For purposes of this section, consultative pathology services must—

(1) Be requested by the patient's attending physician;

(2) Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the patient;

(3) Result in a written narrative report included in the patient's medical record; and

(4) Require the exercise of medical judgment by the consultant physician.

(c) *Independent laboratory services furnished to hospital inpatients.* Laboratory services furnished to a hospital inpatient by an independent laboratory (as defined in § 405.1310(a)) will be reimbursed on a reasonable charge basis under this subpart only if they are physician laboratory services as described in paragraph (a) of this section. Payment for nonphysician services furnished to a hospital inpatient by an independent laboratory will be made by the intermediary to the hospital in accordance with Part 413 of this chapter.

[48 FR 8939, Mar. 2, 1983, as amended at 48 FR 39831, Sept. 1, 1983; 51 FR 34792, Sept. 30, 1986]

§ 405.557 Reasonable charges for physician laboratory services.

The carrier will reimburse a physician for laboratory services that meet the conditions for reasonable charge payment in § 405.556(a) under the reasonable charge rules for physician services in providers in § 405.551 and the general reasonable charges rules in §§ 405.501 through 405.508.

[48 FR 8939, Mar. 2, 1983]

§ 405.580 Conditions of payment for assistants at surgery in teaching hospitals.

(a) *Basis, purpose, and scope.* This section describes the conditions under which Medicare will pay on a reasonable charge basis for the services of an assistant at surgery in a teaching hospital. This section is based on section 1842(b)(6)(D)(i) of the Social Security Act and applies only to hospitals with an approved teaching program. Except as specified in paragraph (c) of this section, reasonable charge reimbursement is not available for assistants at surgery in hospitals with—

(1) A training program relating to the medical specialty required for the surgical procedure; and

(2) A qualified individual on the staff of the hospital available to serve as an assistant at surgery.

(b) *Definitions.* "Assistant at surgery" means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

"Teaching hospital" means a hospital with a graduate education program approved as specified in § 405.522(a).

"Team physicians" means a group of physicians, each performing a discrete, unique function integral to the performance of a complex medical procedure that requires the special skills of more than one physician.

"Qualified individual on the staff of the hospital" means a resident in a training program relating to the specialty required for the surgery.

(c) *Conditions for payment for assistants at surgery.* Beginning October 1, 1982, payment on the basis of reasonable charges may be made for the services of an assistant at surgery in a teaching hospital only if the services—

(1) Are required due to exceptional medical circumstances;

(2) Are performed by team physicians needed to perform complex medical procedures;

(3) Constitute concurrent medical care relating to a medical condition which requires the presence of and active care by a physician of another specialty during surgery; or

(4) Are medically required and are furnished by a physician who is primarily engaged in the field of surgery and the primary surgeon does not utilize interns and residents in the surgical procedures he or she performs (including preoperative and postoperative care).

[47 FR 43653, Oct. 1, 1982, as amended at 48 FR 7176, Feb. 18, 1983]

Subpart F—[Reserved]

Subpart G—Reconsiderations and Appeals Under the Hospital Insurance Program

AUTHORITY: Secs. 1102, 1154, 1155, 1869(b), 1871, 1872 and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c, 1395ff(b), 1395hh, 1395ii and 1395pp).

SOURCE: 37 FR 5814, Mar. 22, 1972, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.701 Basis and purpose.

(a) This subpart implements section 1869 of the Social Security Act. Section 1869(a) provides that the Secretary will make determinations about the following matters, and section 1869(b) provides for a hearing for an individual who is dissatisfied with the Secretary's determination as to:

(1) Whether the individual is entitled to hospital insurance (Part A) or supplementary medical insurance (Part B) under title XVIII of the Act; or

(2) The amount payable under hospital insurance.

(b) This subpart establishes the procedures governing initial determinations, reconsidered determinations, hearings, and final agency review, and the reopening of determinations and decisions that are applicable to matters arising under paragraph (a) of this section.

(c) Subparts J and R of 20 CFR Part 404 (dealing with determinations, the administrative review process and representation of parties) are also applicable to matters arising under paragraph (a) of this section, except to the extent that specific provisions are contained in this subpart.

[45 FR 73932, Nov. 7, 1980, as amended at 50 FR 33031, Aug. 16, 1985]

§ 405.702 Notice of initial determination.

After a request for payment under Part A of title XVIII of the Act is filed with the intermediary by or on behalf of the individual who received inpatient hospital services, extended care services, or home health services, and the intermediary has ascertained whether the items and services furnished are covered under Part A of title XVIII, and where appropriate, ascertained and made payment of amounts due or has ascertained that no payments were due, the individual will be notified in writing of the initial determination in his case. In addition, if the items or services furnished such individual are not covered under Part A of title XVIII by reason of § 405.310(g) or § 405.310(k), and payment may not be made for such items or services under § 405.330 only because the requirements of § 405.330(a)(2) are not met, the provider of services which furnished such items or services will be notified in writing of the initial determination in such individual's case. These notices shall be mailed to the individual and the provider of services at their last known addresses and shall state in detail the basis for the determination. Such written notices shall also inform the individual and the provider of services of their right to reconsideration of the determination if they are dissatisfied with the determination.

[40 FR 1024, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977 and amended at 52 FR 22644, June 15, 1987; 53 FR 6648, Mar. 2, 1988]

§ 405.704 Actions which are initial determinations.

(a) *Applications and entitlement of individuals.* An initial determination with respect to an individual includes the following—

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance;

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence requested by SSA to support the application. (SSA will specify in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence);

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance;

(4) A denial of a request for cancellation of a "request for withdrawal"; and

(5) A determination as to whether an individual, previously determined to be entitled to hospital or supplementary medical insurance, is no longer entitled to such benefits, including a determination based on nonpayment of premiums.

(b) Requests for payment by or on behalf of individuals. An initial determination with respect to an individual includes any determination made on the basis of a request for payment by or on behalf of the individual under Part A of Medicare, including a determination with respect to:

(1) The coverage of items and services furnished;

(2) The amount of an applicable deductible;

(3) The application of the coinsurance feature;

(4) The number of days of inpatient hospital benefits utilized during a spell of illness or for purposes of the inpatient psychiatric hospital 190-day lifetime maximum;

(5) The number of days of the 60-day lifetime reserve utilized for inpatient hospital coverage;

(6) The number of days of posthospital extended care benefits utilized;

(7) The number of home health visits utilized;

(8) The physician certification requirement;

(9) The request for payment requirement;

(10) The beginning and ending of a spell of illness, including a determination made under the presumptions established under § 409.60(c)(2) of this chapter, as specified in § 409.60(c)(4) of this chapter.

(11) The medical necessity of services (See Parts 466 and 473 of this chapter for provisions pertaining to initial and reconsidered determinations made by a PRO);

(12) When services are excluded from coverage as custodial care (§ 405.310(g)) or as not reasonable and necessary (§ 405.310(k)), whether the individual or the provider of services who furnished the services, or both, knew or could reasonably have been expected to know that the services were excluded from coverage (see § 405.332); and

(13) Any other issues having a present or potential effect on the amount of benefits to be paid under Part A of Medicare, including a determination as to whether there has been an overpayment or underpayment of benefits paid under Part A, and if so, the amount thereof; and

(14) Whether a waiver of adjustment or recovery under sections 1870(b) and (c) of the Act is appropriate when an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) has been made with respect to an individual.

(c) *Initial determination with respect to a provider of services.* An initial determination with respect to a provider of services shall be a determination made on the basis of a request for payment filed by the provider under Part A of Medicare on behalf of an individual who was furnished items or services by the provider, but only if the determination involves the following:

(1) A finding by the intermediary that such items or services are not covered by reason of § 405.310(g) or § 405.310(k), and

(2) A finding by the intermediary that either such individual or such provider of services, or both, knew or could reasonably have been expected to know that such items or services were excluded from coverage under the program.

[45 FR 24564, May 1, 1981, as amended at 50 FR 15326, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986; 52 FR 22644, June 15, 1987]

§ 405.705 Actions which are not initial determinations.

An initial determination under Part A of Medicare does not include determinations relating to:

(a) The reasonable cost of items or services furnished under Part A of Medicare;

(b) Whether an institution or agency meets the conditions for participation in the program;

(c) Whether an individual is qualified for use of the expedited appeals process as provided in § 405.718; or

(d) An action regarding compromise of a claim arising under the Medicare program, or termination or suspension of collection action on such a claim under the Federal Claims Collection Act of 1966 (31 U.S.C. 951-953). See 20 CFR 404.515 for overpayment claims against an individual, § 405.374 for overpayment claims against a provider, physician or other supplier, and § 408.110 for claims concerning unpaid Medicare premiums.

[45 FR 73932, Nov. 7, 1980; 46 FR 24565, May 1, 1981, as amended at 52 FR 22454, June 12, 1987; 52 FR 48123, Dec. 18, 1987]

§ 405.706 Decisions of utilization review committees.

(a) *General rule.* A decision of a utilization review committee is a medical determination by a staff committee of the provider or a group similarly composed and does not constitute a determination by the Secretary within the meaning of section 1869 of the Act. The decision of a utilization review committee may be considered by HCFA along with other pertinent medical evidence in determining whether or not an individual has the right to have payment made under Part A of title XVIII.

(b) *Applicability under the prospective payment system.* HCFA may consider utilization review committee decisions related to inpatient hospital services paid for under the prospective payment system (see Part 412 of this chapter) only as those decisions concern:

(1) The appropriateness of admissions resulting in payments under Subparts D, E and G of Part 412 of this chapter.

(2) The covered days of care involved in determinations of outlier payments under § 412.80(a)(1)(i) of this chapter; and

(3) The necessity of professional services furnished in high cost outliers under § 412.80(a)(1)(ii) of this chapter.

[48 FR 39831, Sept. 1, 1983]

§ 405.708 Effect of initial determination.

(a) The initial determination under § 405.704(a) shall be final and binding upon the individual on whose behalf payment under Part A has been requested or, if such individual is deceased, upon the representative of such individual's estate, unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such individual (or the representative of such individual's estate if the individual is deceased) shall be the party to such initial determination.

(b) The initial determination under § 405.704(b) shall be final and binding upon the provider of services unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such provider of services shall be the party to such initial determination.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.710 Right to reconsideration.

(a) An individual who is a party to an initial determination, as specified in § 405.704(a), (or if such individual is deceased, the representative of such individual's estate) and who is dissatisfied with the initial determination may request a reconsideration of such determination in accordance with § 405.711 regardless of the amount in controversy.

(b) A provider of services who is a party to an initial determination (as specified in § 405.704(c)) and who is dissatisfied with such initial determination may request a reconsideration of such determination in accordance with § 405.711, regardless of the amount in controversy, but only if the individual on whose behalf the request for payment was made has indicated in writing that he does not intend to request reconsideration of the intermediary's initial determination on such request for payment, or if the intermediary has made a finding (see § 405.704(c)) that such individual did not know or could not reasonably have been expected to know that the expenses incurred for the items or services for which such request for payment was made were not reimbursable by reason of § 405.310(g) or § 405.310(k).

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977 and amended at 50 FR 33031, Aug. 16, 1985]

§ 405.711 Time and place of filing request for reconsideration.

The request for reconsideration shall be made in writing and filed at an office of the Social Security Administration or the Health Care Financing Administration or, in the case of a qualified railroad retirement beneficiary (see 20 CFR 404.368) filed at an office of the Railroad Retirement Board, within 60 days after the date of receipt of notice of initial determination, unless such time is extended as provided in § 405.712. A request for reconsideration which is filed with the intermediary which received the request for payment submitted on behalf of the individual is considered to have been filed with the Health Care Financing Administration as of the date it is filed with the intermediary. For purposes of this section, the date of receipt of notice of the initial determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.712 Extension of time to request reconsideration.

If a party to an initial determination desires to file a request for reconsideration after the time for filing such request in accordance with § 405.711 has passed, such party may file a petition with the Social Security Administration or the Health Care Financing Administration or, in the case of a qualified railroad retirement beneficiary, with the Railroad Retirement Board, for an extension of time for the filing of such request. Such petition shall be in writing and shall state the reasons why the request for reconsideration was not filed within the required time. For good cause shown, the Health Care Financing Administration may extend the time for filing the request for reconsideration.

§ 405.714 Withdrawal of request for reconsideration.

A request for reconsideration may be withdrawn by the party to the initial determination who filed the request or by his representative provided that the withdrawal is made in writing and filed at an office of the Social Security Administration or the Health Care Financing Administration or, in the case of a qualified railroad retirement beneficiary, with the Railroad Retirement Board prior to the date of the mailing of the notice of reconsidered determination. A withdrawal filed with the intermediary which received the request for payment submitted on behalf of the individual is considered to have been filed with the Health Care Financing Administration as of the date it is filed with the intermediary.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.715 Reconsidered determination.

(a) In reconsidering an initial determination, the Health Care Financing Administration shall review such initial determination, the evidence and findings upon which such determination was based, and any additional evidence submitted to the Social Security Administration or the Health Care Financing Administration or otherwise obtained by the intermediary or the Health Care Financing Administration; and shall make a determination affirming or revising, in whole or in part, such initial determination.

(b) If the request for reconsideration is filed by an individual with respect to an initial determination specified in § 405.704(a)(12), the provider of services who furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto. If pursuant to § 405.710(b) a request for reconsideration is filed by a provider of services with respect to an individual determination under § 405.704(b), the individual who was furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.716 Notice of reconsidered determination.

Written notice of the reconsidered determination shall be mailed by the Health Care Financing Administration to the parties and their representatives at their last known addresses. Such notice shall state the specific reasons for the reconsidered determination and shall advise the parties of their right to a hearing if the amount in controversy is $100 or more, or, if appropriate, advise them of the requirements for use of the expedited appeals process (see § 405.718).

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.717 Effect of a reconsidered determination.

The reconsidered determination shall be final and binding upon all parties unless a request for a hearing is filed with the Social Security Administration or the Health Care Financing Administration within 60 days after the date of receipt of notice of the reconsidered determination by such parties, or unless the reconsidered determination is revised in accordance with the provisions of § 405.750, or unless the expedited appeals process is used in accordance with § 405.718a. For purposes of this section, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718 Expedited appeals process; conditions for use of such process.

In cases in which a reconsideration determination has been made or a higher level of appeal has been reached, an expedited appeals process may be used in lieu of the hearing and

Appeals Council review, if the following conditions are met:

(a) A reconsideration determination has been made by the Secretary; and

(b) The individual is a party referred to in § 405.718b; and

(c) The individual has filed a written request for the expedited appeals process; and

(d) The individual has alleged, and the Secretary agrees, that the only factor precluding a favorable determination with respect to a matter referred to in § 405.704, is a statutory provision which the individual alleges to be unconstitutional; and

(e) Where more than one individual is a party referred to in § 405.718b, each and every party concurs in the request for the expedited appeals process.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718a Expedited appeals process; place and time of filing request.

(a) *Place of filing request.* The request for the expedited appeals process must be made in writing and filed:

(1) At an office of the Social Security Administration or the Health Care Financing Administration; or

(2) In the case of an individual in the Philippines, at the Veterans Administration Regional Office in the Philippines or with a presiding officer; or

(3) In the case of a qualified railroad retirement beneficiary (see 20 CFR 404.368), at an office of the Railroad Retirement Board.

(b) *Time of filing request.* The request for the expedited appeals process must be filed at one of the following times:

(1) No later than 60 days after the date of receipt of notice of the reconsidered determination, unless the time is extended in accordance with the standards set out in 20 CFR 404.925(c). For purposes of this paragraph, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary; or

(2) If a request for hearing has been timely filed (see § 405.722), at any time prior to the individual's receipt of notice of the presiding officer's decision; or

(3) Within 60 days after the date of receipt of notice of the presiding officer's decision or dismissal, unless the time is extended in accordance with the standards set out in 20 CFR 404.925(c). For purposes of this paragraph, the date of receipt of notice of the presiding officer's decision or dismissal shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary; or

(4) If a request for review by the Appeals Council has been timely filed (see 20 CFR 404.968) at any time prior to receipt by such individual of notice of the Appeals Council's final action.

[40 FR 53387, Nov. 18, 1975, as amended at 41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 45 FR 73933, Nov. 7, 1980]

§ 405.718b Expedited appeals process; parties.

The parties to the expedited appeals process shall be the person or persons who were parties to the reconsideration determination in question and, if appropriate, parties to the hearing.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718c Expedited appeals process; agreement requirements.

(a) (1) An authorized representative of the Secretary shall, if he determines that all conditions for the use of the expedited appeals process are met (see § 405.718), prepare an agreement for signature of the party (parties) and an authorized representative of the Secretary.

(2) (i) Where a request for hearing has been filed, but prior to issuance of a decision a request for the expedited appeals process is filed, the Chief Administrative Law Judge of the Bureau of Hearings and Appeals, or his designee, shall determine if the conditions required for entering an agreement are met.

(ii) Where a hearing decision was the last action, or where a request for review is pending before the Appeals Council, and a request for the expedited appeals process is filed, the Chairman or Deputy Chairman of the Appeals Council or the Chairman's designee, shall determine if the conditions required for an agreement are met.

(b) An agreement with respect to the expedited appeals process shall provide that:

(1) The facts involved in the claim are not in dispute; and

(2) Except as indicated in paragraph (b)(3) of this section, the Secretary's interpretation of the law is not in dispute; and

(3) The sole issue(s) in dispute is the application of a statutory provision(s) which is described therein and which is alleged to be unconstitutional by the party requesting use of such process; and

(4) Except for the provision challenged, the right(s) of the party is established; and

(5) The determination or decision made by the Secretary is final for purposes of section 205(g) of the Act.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718d Expedited appeals process; effect of agreement.

The agreement described in § 405.718c, when signed, shall constitute a waiver by the parties and the Secretary with respect to the need of the parties to pursue the remaining steps of the administrative appeals process, and the period for filing a civil action in a district court of the United States, as provided in section 205(g) of the Social Security Act, shall begin as of the date on which the party (parties) and the authorized representative of the Secretary sign the agreement. Any civil action under the expedited appeals process must be filed within 60 days following the date on which the agreement is signed by, or on behalf of, the Secretary.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718e Effect of a request that does not result in agreement.

If a request for the expedited appeals process does not meet all the conditions for the use of the process, the Secretary shall so advise the party (parties) and shall treat the request as a request for reconsideration, a hearing, or Appeals Council review, whichever is appropriate.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.720 Hearing; right to hearing.

A person has a right to a hearing regarding any initial determination made under § 405.704 if:

(a) Such initial determination has been reconsidered by the Health Care Financing Administration;

(b) Such person was a party to the reconsidered determination;

(c) Such person or his representative has filed a written request for a hearing in accordance with the procedure described in § 405.722; and

(d) The amount in controversy is $100 or more.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.722 Time and place of filing request for a hearing.

The request for a hearing shall be made in writing and filed at an office of the Social Security Administration or the Health Care Financing Administration or with a presiding officer, or, in the case of a qualified railroad retirement beneficiary, at an office of the Railroad Retirement Board. Such request must be filed within 60 days after the date of receipt of notice of the reconsidered determination by such individual, except where the time is extended as provided in 20 CFR 404.933(c). For purposes of this section, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[45 FR 73933, Nov. 7, 1980]

§ 405.724 Appeals Council review.

Appeals Council review is provided by 20 CFR 404.967.

[45 FR 73933, Nov. 7, 1980]

§ 405.730 Court review.

To the extent authorized by section 1869, section 1876(f), and section 1879(d) of the Act, a party to a decision of the Appeals Council (see 20

CFR 404.979) or the decision of a presiding officer where the request for review by the Appeals Council was denied, may obtain a court review where the amount in controversy after Appeals Council review is $1,000 or more, by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act (see 20 CFR 422.210 for the filing procedure). A party to a reconsidered determination may obtain a court review where the amount in controversy is $1,000 or more and he requests and meets the conditions for the expedited appeals process (see § 405.718).

[45 FR 73933, Nov. 7, 1980]

§ 405.740 Principles for determining the amount in controversy.

The following principles shall be applicable for purposes of determining the amount in controversy:

(a) The amount in controversy should be computed as the actual amount charged the individual for the items and services in question less deductible and coinsurance amounts applicable in the particular case.

(b) Where direct payment is made to an individual in accordance with § 424.53 of this chapter, the amount in controversy should be computed as 60 percent and 80 percent respectively, of the hospital's reasonable charges for routine and ancillary services furnished after the applicable deductible and coinsurance amounts have been applied.

(c) Where the issues in dispute relate to services furnished to a patient of a provider of services, all items or services in dispute arising from a single continuous period of treatment shall be considered in determining the amount in controversy.

(d) The principle set forth in paragraph (c) of this section shall be applicable even when more than one request for payment is submitted and notice of utilization issued, because of the provider's billing practices.

(e) Any series of posthospital home health visits shall be considered collectively in determining the amount in controversy.

(f) Appeals from determinations pertaining to inpatient hospital services, extended care services or posthospital home health services shall not ordinarily be additive for purposes of determining the amount in controversy except, where:

(1) The denial of payment for inpatient hospital services prevents the individual from meeting a condition precedent for payment for extended care or home health services; or

(2) The same factor is at issue in more than one claim for benefits by such individual (e.g., an individual, during June, is hospitalized twice; in each case the claim for payment is denied on the basis that the hospitalization occurred during an ongoing spell of illness which began prior to June and in which the individual had already utilized all available benefit days; the individual appeals claiming that he was in a new spell of illness and had the full number of benefit days available).

(g) Notwithstanding the provisions of paragraphs (b) through (f) of this section a presiding officer may hear several issues in a single hearing but only where the requirement of § 405.720(d) is satisfied with respect to each such issue.

(h) Notwithstanding the provisions of paragraph (a) of this section, when payment is made for certain non-reimbursable expenses pursuant to § 405.330, or the liability of the individual is limited for certain noncovered items or services pursuant to § 405.331, the amount in controversy should be computed as the amount that would have been charged the individual for the items and services in question, less deductible and coinsurance amounts applicable in the particular case, had such expenses not been paid pursuant to § 405.330 or had such liability not been limited pursuant to § 405.331.

[37 FR 5814, Mar. 22, 1972, as amended at 40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 6648, Mar. 2, 1988]

§ 405.741 Presiding officer determines amount in controversy.

The determination as to whether the amount of benefits in controversy is $100 or more in order to qualify the issue for a hearing shall be made by the presiding officer.

§ 405.745 Amount in controversy ascertained after reconsideration.

For the purpose of determining whether a party to a reconsidered determination is entitled to a hearing, the amount in controversey after the reconsideration action rather than the amount in controversy initially at issue shall be controlling.

[40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.747 Dismissal of request for hearing; amount in controversy less than $100.

The presiding officer shall, without holding a hearing, dismiss the request for hearing if the request for hearing plainly shows that less than $100 is in controversy. If a hearing is held and the presiding officer finds that the amount in controversy is less than $100, the presiding officer shall dismiss the request for hearing and will not rule on the substantive issues involved in the appeal.

§ 405.750 Time period for reopening initial, revised, or reconsidered determinations and decisions or revised decisions of a presiding officer or the Appeals Council; finality of determinations and decisions.

(a) *Reopenings concerning applications and entitlement.* A determination, or decision, or revised determination or decision made by the Social Security Administration concerning any matter under § 405.704(a), may be reopened and revised under 20 CFR 404.988 (Conditions for reopening).

(b) *Reopenings concerning a request for payment.* An initial, revised, or reconsidered determination of the Health Care Financing Administration, or a decision or revised decision of a presiding officer or of the Appeals Council, with respect to an individual's rights concerning a request for payment under Part A of Medicare, which is otherwise final under 20 CFR 404.955 or 404.981 and 405.708, or 405.717 of this subpart may be reopened:

(1) Within 12 months from the date of the notice of the initial or reconsidered determination to the party to such determination;

(2) After such 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.988(b) and 404.989); or

(3) At any time, when:

(i) Such initial, revised, or reconsidered determination or such decision or revised decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting clerical error or error on the face of the evidence on which such determination or decision was based; or

(ii) Such initial, revised, or reconsidered determination or such decision or revised decision was procured by fraud or similar fault of the beneficiary or some other person.

[45 FR 73933, Nov. 7, 1980]

Subpart H—Review and Hearing Under the Supplementary Medical Insurance Program

AUTHORITY: Secs. 1102, 1831-1843, 1871, 49 Stat. 647, as amended, 79 Stat. 301-313; 79 Stat. 331; 42 U.S.C. 1302, 1395 et seq.

SOURCE: 32 FR 18028, Dec. 16, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.801 Title XVIII, Part B—General.

(a) Section 1842(b)(3)(C) of the Act provides that a carrier shall establish and maintain procedures under which an individual enrolled in the supplementary medical insurance plan (see Subpart B of this Part) is provided with the opportunity for a hearing by the carrier when the amount in controversy is $100 or more as determined in accordance with § 405.820(b) and he is dissatisfied with the carrier's determination denying a request for payment, or with the amount of payment under the supplementary medical insurance plan or when he believes that the request for payment is not being acted upon with reasonable promptness. A physician or other person who furnishes items or services to a person enrolled under the supplementary medical insurance plan and who accepts an assignment from the enrollee has the same right as the enrollee to appeal the carrier's determination.

(b) As used in this section, the term "with reasonable promptness" shall mean a period of 60 consecutive days after the receipt by the carrier of a request for payment.

(c) Procedures governing determinations as to whether an individual is entitled to supplementary medical insurance, which implement section 1869(a) of the Social Security Act, are covered in Subpart G of this part and 20 CFR Part 404, Subpart J.

[39 FR 12096, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 45 FR 73945, Nov. 7, 1980]

§ 405.802 Definitions.

As used in this Subpart H the term:

(a) "Carrier" means an organization which has entered into a contract with the Secretary pursuant to section 1842 of the Act and which is authorized to make determinations with respect to Part B of title XVIII of the Social Security Act.

(b) "Party" means a person enrolled under Part B of title XVIII, his assignee, or other entity having standing in the initial or appellate proceedings.

(c) "Assignor" means a person meeting the enrollment requirements under Part B of title XVIII for payment of the claim being assigned.

(d) "Assignee" means a physician or other person who furnished covered services to an assignor under the supplementary medical insurance plan and who has accepted a valid assignment executed by such assignor.

(e) "Assignment" means the transfer by the assignor (defined in paragraph (c) of this section) of his claim for payment to the assignee (defined in paragraph (d) of this section) in return for the latter's promise not to charge more for his services than the carrier finds to be the reasonable charges.

(f) "Representative" means an individual meeting the conditions described in §§ 405.870-405.871.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12096, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.803 Initial determination.

(a) The carrier (or the hearing officer where a claim is "not acted upon with reasonable promptness" (see § 405.801)) shall, on the basis of all of the evidence, make an initial determination with respect to an applicant's claim for benefits under Part B of title XVIII.

(b) An initial determination for purposes of this subpart includes among others, a determination as to whether items and services furnished are covered; whether the deductible has been met; whether the receipted bill or other evidence of payment is acceptable; whether the charges for items or services furnished are reasonable; and if the items or services furnished an enrollee by a physician or a supplier of services pursuant to an assignment under § 424.55 of this chapter are not covered by reason of § 405.310(k), whether such enrollee, physician, or supplier knew or could reasonably have been expected to know that such items or services were excluded from coverage.

(c) Carriers (or hearing officers where a claim is not acted upon with reasonable promptness (see § 405.801)) do not make determinations with respect to the following, which are not initial determinations for purposes of this subpart:

(1) Any issue or factor for which the Social Security Administration or the Health Care Financing Administration has sole responsibility (for example, whether an independent laboratory meets the conditions for coverage of services; whether a Medicare overpayment claim should be compromised, or collection action terminated or suspended); or

(2) Any issue or factor which relates to hospital insurance benefits under Part A of title XVIII of the Act.

[39 FR 12097, Apr. 3, 1974, as amended at 40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 59382, Dec. 20, 1978, 45 FR 73945, Nov. 7, 1980; 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988]

§ 405.804 Notice of initial determination.

After a carrier has made an initial determination on a request for payment written notice of this determination shall be mailed to each party to the determination at his last known address. The notice of the determination shall inform each party to the determination of his right to have such determination reviewed.

§ 405.805 Parties to the initial determination.

The parties to the initial determination (see § 405.803) may be any party described in § 405.802(b).

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.806 Effect of initial determination.

The initial determination shall be final and binding upon the party or parties to such determination unless it is reviewed in accordance with §§ 405.810 through 405.812, or is revised in accordance with § 405.841 by the carrier (or by the hearing officer presiding where a claim is not acted upon with reasonable promptness (see § 405.801)).

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.807 Review of initial determination.

(a) *General.* A party to an initial determination by a carrier, who is dissatisfied with such initial determination, may request that the carrier review such determination. If a review is requested, such action shall not constitute a waiver of the right to hearing (see § 405.820) subsequent to such review.

(b) *Place of filing request.* A request for a carrier to review the initial determination is to be made in writing and filed at an office of the carrier or at an office of the Social Security Administration or the Health Care Financing Administration.

(c) *Time of filing request.* The carrier shall provide a period of 6 months after the date of the notice of its initial determination within which a party to the initial determination may request review. The carrier may, upon request by the party affected, extend the period for requesting the review.

(d) *Request for review.* Any clear expression in writing by a party to an initial determination which indicates, in effect, that he is dissatisfied with such determination by the carrier and wants to appeal the matter further constitutes a request for review.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.808 Parties to the review.

The parties to the review (as provided for in § 405.807(a)) shall be the persons who were parties to the carrier's initial determination as described in § 405.805, and any other party whose rights with respect to the particular claim being reviewed may be affected by such review.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.809 Opportunity to submit evidence.

The parties to the review (as provided for in § 405.807(a)) shall have a reasonable opportunity to submit written evidence and contentions as to fact or law relative to the claim at issue.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.810 Review determination.

Subject to the provisions of §§ 405.807 through 405.809, the carrier shall review the claim in dispute and, upon the basis of the evidence of record, shall make a separate determination affirming or revising in whole or in part the findings and determination in question.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.811 Notice of review determination.

Written notice of the determination after review shall be mailed to the parties thereto at their last known addresses. The review determination shall state the basis therefor and advise the parties of their right to a hearing when the amount in controversy is $100 or more as determined in accordance with § 405.820(b). The notice will state the place and manner of requesting a hearing as well as the time limit during which a hearing must be requested (see §§ 405.820 and 405.821).

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.812 Effect of review determination.

The review determination shall be final and binding upon all parties to such review unless a hearing determination is rendered pursuant to a request made in accordance with § 405.821 or is revised in accordance with § 405.841.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.820 Right to hearing.

(a) *General.* Any party designated in § 405.822 shall be entitled to a hearing after a review determination has been made by the carrier if the amount in controversy is $100 or more as determined in accordance with paragraph (b) of this section when such party files a written request for a hearing.

(b) *Amount in controversy.* For the purpose of determining an individual's right to a hearing under paragraph (a) of this section:

(1) The amount in controversy shall be computed as the actual amount charged the individual for the items and services in question, less any amount for which payment has been made by the carrier and less any deductible and coinsurance amounts applicable in the particular case.

(2) Any series of claims by the same party or parties to the determinations for which the requests for hearing have been timely filed but on which no decisions by a hearing officer have previously been made shall be considered collectively in determining the amount in controversy.

(3) The determination as to whether the amount in controversy is $100 or more shall be made by the hearing officer.

(4) Notwithstanding the provisions of paragraph (b)(1) of this section, when payment is made for certain nonreimbursable expenses pursuant to § 405.330 or the liability of the individual is limited for certain noncovered items or services pursuant to § 405.331, the amount in controversy shall be computed as the amount that would have been charged the individual for the items or services in question, less any deductible and coinsurance amounts applicable in the particular case, had such expenses not been paid pursuant to § 405.330 or had such liability not been limited pursuant to § 405.331.

(c) *Place of filing request.* The hearing request must be filed at an office of the carrier or at an office of the Social Security Administration or the Health Care Financing Administration.

(d) *Time of filing request.* Except where the initial determination has been made at a hearing (where a claim is not acted upon with reasonable promptness (see § 405.801), there shall be provided a period of 6 months after the date of the notice of the review determination within which a party to the initial or review determination may request a hearing. The carrier may, upon request by the party affected, extend the period for filing the request for hearing.

[39 FR 12097, Apr. 3, 1974, as amended at 40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.821 Request for hearing.

A request for a hearing is any clear expression in writing by a claimant asking for a hearing to adjudicate his claim when not acted upon with reasonable promptness, or by a party to a review determination which states, in effect, that he is dissatisfied with the carrier's review determination and wants further opportunity to appeal the matter to the carrier.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.822 Parties to a hearing.

The parties to a hearing shall be the persons who were parties to the carrier's review determination (§ 405.808) which is in question. Any other person may be made a party if that person's rights with respect to supplementary medical insurance benefits may be prejudiced by the decision.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.823 Hearing officer.

Any hearing provided for in this subpart shall be conducted by a hearing officer designated by the appropriate official of the carrier.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.824 Disqualification of hearing officer.

A hearing officer shall not conduct a hearing in any case in which he is prejudiced or partial with respect to any party, or if he has any interest in the matter before him. Notice of any objection with respect to the hearing officer who will conduct the hearing shall be made by the objecting party at his earliest opportunity. The hearing officer shall consider such objection and shall, at his discretion, withdraw. If the hearing officer withdraws, the appropriate official of the carrier shall designate another hearing officer to conduct the hearing. If the hearing officer does not withdraw, the objecting party may present his objections to the carrier for consideration at any time prior to the issuance of a decision. The carrier shall review the request and take appropriate action. The fact that a hearing officer is an employee of the carrier may not serve as prima facie cause for disqualification.

§ 405.825 Location of hearing.

(a) *Time and place.* The hearing officer shall fix a time and place for the hearing reasonably convenient to the requesting party and not inconsistent with the public interest.

(b) *Adjournment or postponement.* The hearing officer may, for a good and sufficient reason, fix a new time and/or place for the hearing; he may change the time and place for the hearing or adjourn the hearing on his own motion upon reasonable notification to the parties.

§ 405.826 Notice of hearing.

The notice of hearing is to include notice of the time and place of the hearing; information as to the specific issues to be determined; and the matters on which findings will be made and conclusions will be reached. The notice is to contain sufficient information about the hearing procedure (including the party's right to representation) for effective preparation for the hearing.

§ 405.830 Conduct of the hearing.

(a) *General.* Hearings shall be open to the parties and to such other persons as the hearing officer deems necessary and proper for the orderly and efficient conduct of the hearing. The hearing officer shall inquire fully into the matters at issue and shall receive in evidence the testimony of witnesses and any documents which are relevant and material to such matters. The parties shall be provided an opportunity to enter any objection to the inclusion of any document. The order in which evidence and allegations shall be presented and the procedure at the hearing, except as this subpart otherwise expressly provides, shall be at the discretion of the hearing officer and of such nature as to afford the parties a proper hearing.

(b) *Evidence.* Evidence may be received at the hearing even though inadmissible under rules of evidence applicable to court procedures.

(c) *Witnesses.* The hearing officer may examine the witnesses and shall allow the parties or their representatives to do so. If the hearing officer conducts the examination of a witness, he may allow the parties to suggest matters upon which they desire the witness to be questioned, and the hearing officer shall question the witness with respect to such matters if they are relevant and material to any issue pending for decision before him.

(d) *Oral argument and written allegations.* The parties, upon their request shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements or allegations of facts or law.

(e) *Consolidated issues.* When one or more new issues are raised at any time after a request for hearing has been made, but before the mailing of notice of the decision, the hearing officer may, at his discretion, consider the issues along with the other issues pending before him on the same request for hearing.

§ 405.831 Waiver of right to appear and present evidence.

If all parties waive their right to appear before the hearing officer and present evidence and contentions personally or by representative, it shall not be necessary for the hearing officer to give notice of or conduct a formal hearing as provided in §§ 405.825 through 405.830. A waiver of the right to appear is to be in writing and filed with the hearing officer or the carrier. Such waiver may be withdrawn by a party at any time prior to the mailing of notice of the decision in the case. Even though all of the parties have filed a waiver of the right to appear and present evidence and contentions at a hearing before the hearing officer, the hearing officer may, nevertheless, give notice of a time and place and conduct a hearing as provided in §§ 405.825 through 405.830, if he believes that the personal appearance and testimony of the party or parties would assist him to ascertain the facts at issue in the case. For purposes of this section, failure of the parties to appear shall not be cause for a finding of abandonment and the hearing officer shall make his decision on the basis of all evidence adduced.

§ 405.832 Dismissal of request for hearing.

(a) *By application of party.* With the approval of the hearing officer, a request for a hearing may be withdrawn or dismissed at any time prior to the mailing of notice of the decision upon the application of the party or parties filing the request for such hearing. A party may request a dismissal by filing a written notice of such request with the carrier, the hearing officer or orally stating such request at the hearing. The dismissal of a request for hearing shall be final and binding unless vacated (see paragraph (d) of this section).

(b) *Dismissal by abandonment of party.* A hearing officer may dismiss a request for hearing upon abandonment by the party or parties who filed the request. A party shall be deemed to have abandoned a request for hearing, other than where personal appearance is waived in accordance with § 405.831, if neither the party nor his representative appears at the time and place fixed for the hearing and within 10 days after the mailing of a notice to him by the hearing officer to show cause, such party does not show good and sufficient cause for such failure to appear and failure to notify the hearing officer prior to the time fixed for hearing that he cannot appear.

(c) *Dismissal for cause.* The hearing officer may, on his own motion, dismiss a hearing request, either entirely or as to any stated issue, under either of the following circumstances:

(1) Where the party requesting a hearing is not a proper party under § 405.822 or does not otherwise have a right to a hearing under section 1842(b)(3)(c) of the Act; or

(2) Where the party who filed the hearing request dies and there is no information before the hearing officer showing that an individual who is not a party may be prejudiced by the carrier's determination.

(d) *Dismissal without prejudice.* The hearing officer may on his own motion dismiss without prejudice a hearing request where the amount in controversy is less than $100.

(e) *Vacation of dismissal.* A hearing officer may, on request of a party and for good and sufficient cause shown, vacate any dismissal of a request for hearing at any time within 6 months from the date of mailing notice of the dismissal to the party requesting the hearing at his last known address.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.833 Record of hearing.

A complete record of the proceedings at the hearing shall be made. The testimony shall be transcribed and copies of other documentary evidence shall be reproduced in any case when directed by the hearing officer, the carrier or the Health Care Financing Administration. The record will also be transcribed and reproduced at the request of a party to the hearing provided he bears the cost thereof.

§ 405.834 Hearing officer's decision.

As soon as practicable after the close of a hearing, the hearing officer, except as provided in this subpart, shall make a decision in the case which shall be based upon the evidence adduced at the hearing (see §§ 405.820 to 405.830) or otherwise included in the hearing record (see § 405.833). The decision shall be made in writing and contain findings of fact and statement of reasons. A copy of the decision shall be mailed to each party to the hearing at his last known address.

§ 405.835 Effect of hearing officer's decision.

The hearing officer's decision, provided for in § 405.834, shall be final and binding upon all parties to the hearing unless it is revised in accordance with § 405.841.

§ 405.841 Reopening initial or review determination of the carrier, and decision of a hearing officer.

An initial or review determination of a carrier or a decision of a hearing officer may be reopened by such carrier or hearing officer:

(a) Within 12 months from the date of the notice of such initial or review determination or decision to the party to such determination or decision; or

(b) After such 12-month period, but within 4 years from the date of the notice of the initial determination to the party to such determination, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.958); or

(c) At any time, when:

(1) Such initial or review determination or decision was procured by fraud or similar fault of the beneficiary or some other person, or

(2) Such initial or review determination or decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error or error on the face of the evidence on which such determination or decision was based.

[39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.842 Notice of reopening and revision.

(a) *Notice.* When any determination or decision is reopened as provided in § 405.841, notice of such reopening shall be mailed to the parties to such determination or decision at their last known addresses. A notice of revision following a reopening of a decision, shall be mailed to the parties and shall state the basis for the revised determination or decision.

(b) *Effect of revised determination.* The revision of a determination (see § 405.841) shall be final and binding upon all parties thereto unless a party files a written request for a hearing with respect to a revised determination when the amount in controversy is $100 or more.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.850 Change of ruling or legal precedent.

Change of a legal interpretation or administrative ruling upon which a determination or decision was made shall not be considered as good and sufficient reason for reopening the determination or decision.

§ 405.860 Authority of the hearing officer.

The hearing officer in exercising the authority to conduct a hearing under section 1842(b)(3)(C) of the Act is to comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with policy statements, instructions and other guides issued by the Health Care Financing Administration in accordance with the Secretary's agreement with the carriers.

§ 405.870 Appointment of representative.

A party to an initial determination, informal review or hearing as provided in §§ 405.803 through 405.934, may appoint as his representative in any such proceeding any person qualified under § 405.871. Where the representative is an attorney, in the absence of information to the contrary, his representation that he has such authority shall be accepted as evidence of the attorney's authority to represent a party.

§ 405.871 Qualifications of representatives.

Any individual may be appointed to act as representative in accordance with § 405.870, unless he is disqualified or suspended from acting as a representative in proceedings before the Social Security Administration or the Health Care Financing Administration or unless otherwise prohibited by law.

§ 405.872 Authority of representatives.

A representative, appointed and qualified as provided in §§ 405.870 and 405.871, may make or give, on behalf of the party he represents, any request or notice relative to any proceeding before the carrier including review and hearing. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to the claim of such party to the same extent as such party. Notice to any party or any action, determination, or decision, or request to any party for the production of evidence, shall be sent to the representative of such party.

Subparts I and J—[Reserved]

Subpart K—Conditions of Participation; Skilled Nursing Facilities

AUTHORITY: Secs. 1102, 1814, 1832, 1833, 1861, 1863, 1865, 1866, 1871, of the Social Security Act; 42 U.S.C. 1302, 1395f, 1395k, 1395l, 1395x, 1395z, 1395bb, 1395cc, 1395hh.

SOURCE: 39 FR 2240, Jan. 17, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1101 Definitions.

As used in this subpart, the following definitions apply:

(a) *Administrator of skilled nursing facility.* A person who:

(1) Is licensed as required by State law; or

(2) If the State does not have a Medicaid program, and has no licensure requirement, is a high school graduate (or equivalent), has completed courses in administration or management approved by the appropriate State agency, and has 3 years of supervisory management experience in a skilled nursing facility or related health program; or

(3) If the administrator of a hospital in which there is a hospital-based distinct-part skilled nursing facility, in a State that does not license skilled nursing facility administrators, meets the requirements of § 482.12(b).

(b) *Approved drugs and biologicals.* Only such drugs and biologicals as are:

(1) In the case of Medicare:

(i) Included (or approved for inclusion) in the United States Pharmacopoeia, National Formulary, or United States Homeopathic Pharmacopoeia; or

(ii) Included (or approved for inclusion) in AMA Drug Evaluations or Accepted Dental Therapeutics, except for any drugs and biologicals unfavorably evaluated therein; or

(iii) Not included (nor approved for inclusion) in the compendia listed in paragraphs (b) (1) (i) and (b) (1) (ii) of this section, may be considered approved if such drugs:

(A) Were furnished to the patient during his prior hospitalization, and

(B) Were approved for use during a prior hospitalization by the hospital's pharmacy and drug therapeutics committee (or equivalent), and

(C) Are required for the continuing treatment of the patient in the facility.

(2) In the case of Medicaid, those drugs approved by the State Title XIX agency.

(c) *Charge nurse.* A person who is:

(1) Licensed by the State in which practicing as a:

(i) Registered nurse; or

(ii) Practical (vocational) nurse who:

(A) Is a graduate of a State-approved school of practical (vocational) nursing; or

(B) Has 2 years of appropriate experience following licensure by waiver as a practical (vocational) nurse, and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, or on a State licensure examination which the Secretary finds at least equivalent to the proficiency examination, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State or seeking initial qualifications as a practical (vocational) nurse after December 31, 1977; and

(2) Is experienced in nursing service administration and supervision and, in areas such as rehabilitative or geriat-

ric nursing, or acquires such preparation through formal staff development programs.

In the case of skilled nursing facility services in an institution for the mentally retarded or in an institution for those with mental diseases, or a distinct part thereof, a person licensed in another category of health care discipline who has special training in the care of such patients may serve as charge nurse provided that such person is licensed in such category by the State following completion of a course of training which included at least the number of classroom and practice hours in all the nursing subjects included in the program of a State-approved school of practical (vocational) nursing, as evidenced by a report on comparison of the courses in the respective curricula to the State agency by the agency(ies) of the State responsible for the licensure of such personnel. (An institution primarily engaged in the care of the mentally retarded or in the treatment of mental diseases cannot qualify as a participating skilled nursing facility under Medicare.)

(d) *Controlled drugs.* Drugs listed as being subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-513) as set forth in 21 CFR Part 308.

(e) *Dietetic service supervisor.* A person who:

(1) Is a qualified dietitian; or

(2) Is a graduate of a dietetic technician or dietetic assistant training program, corresponding or classroom, approved by the American Dietetic Association; or

(3) Is a graduate of a State-approved course that provided 90 or more hours of classroom instruction in food service supervision and has experience as a supervisor in a health care institution with consultation from a dietitian; or

(4) Has training and experience in food service supervision and management in a military service equivalent in content to the program in paragraph (e)(2) or (e)(3) of this section.

(f) *Dietitian (qualified consultant).* A person who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on January 17, 1974; or

(2) Has a baccalaureate degree with major studies in food and nutrition, dietetics, or food service management, has 1 year of supervisory experience in the dietetic service of a health care institution, and participates annually in continuing dietetic education.

(g) *Director of nursing services.* A registered nurse who is licensed by the State in which practicing, and has 1 year of additional education or experience in nursing service administration, as well as additional education or experience in such areas as rehabilitative or geriatric nursing, and participates annually in continuing nursing education.

(h) *Drug administration.* An act in which a single dose of a prescribed drug or biological is given to a patient by an authorized person in accordance with all laws and regulations governing such acts. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container), verifying it with the physician's orders, giving the individual dose to the proper patient, and promptly recording the time and dose given.

(i) *Drug dispensing.* An act entailing the interpretation of an order for a drug or biological and, pursuant to that order, the proper selection, measuring, labeling, packaging, and issuance of the drug or biological for a patient or for a service unit of the facility.

(j) *Existing buildings.* For purposes of ANSI Standard No. A117.1 and minimum patient room size (see § 405.1134 (c) and (e)) in skilled nursing facilities or parts thereof whose construction plans are approved and stamped by the appropriate State agency responsible therefore before the date these regulations become effective.

(k) *Licensed nursing personnel.* Registered nurses or practical (vocational) nurses licensed by the State in which practicing.

(l) *Medical record practitioner (qualified consultant).* A person who:

(1) Is eligible for certification as a registered record administrator (RRA), or an accredited record techni-

cian (ART), by the American Medical Record Association under its requirements in effect on the publication of this provision; or

(2) Is a graduate of a school of medical record science that is accredited jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association.

(m) *Occupational therapist (qualified consultant).* A person who:

(1) Is a graduate of an occupational therapy curriculum accredited jointly by the Council on Medical Education of the American Medical Association and the American Occupational Therapy Association; or

(2) Is eligible for certification by the American Occupational Therapy Association under its requirements in effect on the publication of this provision; or

(3) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State or seeking initial qualifications as an occupational therapist after December 31, 1977.

(n) *Occupational therapy assistant.* A person who:

(1) Is eligible for certification as a certified occupational therapy assistant (COTA) by the American Occupational Therapy Association under its requirements in effect on the publication of this provision; or

(2) Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determination of proficiency shall not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

(o) *Patient activities coordinator (qualified consultant).* A person who:

(1) Is a qualified therapeutic recreation specialist; or

(2) Has 2 years of experience in a social or recreational program within the last 5 years, 1 year of which was full-time in a patient activities program in a health care setting; or

(3) Is a qualified occupational therapist or occupational therapy assistant.

(p) *Pharmacist.* A person who:

(1) Is licensed as a pharmacist by the State in which practicing, and

(2) Has training or experience in the specialized functions of institutional pharmacy, such as residencies in hospital pharmacy, seminars on institutional pharmacy, and related training programs.

(q) *Physical therapist (qualified consultant).* A person who is licensed as a physical therapist by the State in which practicing, and

(1) Has graduated from a physical therapy curriculum approved by the American Physical Therapy Association, or by the Council on Medical Education and Hospitals of the American Medical Association, or jointly by the Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(2) Prior to January 1, 1966, was admitted to membership by the American Physical Therapy Association, or was admitted to registration by the American Registry of Physical Therapists, or has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(3) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(4) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring physicians; or

(5) If trained outside the United States, was graduated since 1928 from a physical therapy curriculum approved in the country in which the

curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy, meets the requirements for membership in a member organization of the World Confederation for Physical Therapy, has 1 year of experience under the supervision of an active member of the American Physical Therapy Association, and has successfully completed a qualifying examination as prescribed by the American Physical Therapy Association.

(r) *Physical therapist assistant.* A person who is licensed as a physical therapist assistant, if applicable, by the State in which practicing, and

(1) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(2) Has 2 years of appropriate experience as a physical therapist assistant, and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapist assistant after December 31, 1977.

(s) *Social worker (qualified consultant).* A person who is licensed, if applicable, by the State in which practicing, is a graduate of a school of social work accredited or approved by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

(t) *Speech pathologist or audiologist (qualified consultant).* A person who is licensed, if applicable, by the State in which practicing, and

(1) Is eligible for a certificate of clinical competence in the appropriate area (speech pathology or audiology) granted by the American Speech and Hearing Association under its requirements in effect on the publication of this provision; or

(2) Meets the educational requirements for certification, and is in the process of accumulating the supervised experience required for certification.

(u) *Supervision.* Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity within his sphere of competence, with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Unless otherwise stated in regulations, the supervisor must be on the premises if the person does not meet assistant-level qualifications specified in these definitions.

(v) *Therapeutic recreation specialist (qualified consultant).* A person who is licensed or registered, if applicable, by the State in which practicing, and is eligible for registration as a therapeutic recreation specialist by the National Therapeutic Recreation Society (Branch of National Recreation and Park Association) under its requirements in effect on publication of this provision.

[39 FR 2240, Jan. 17, 1974, as amended at 39 FR 35775, Oct. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 22040, June 17, 1986]

§ 405.1120 Condition of participation—compliance, with Federal, State, and local laws.

The skilled nursing facility is in compliance with applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure.* The facility, in any State in which State or applicable local law provides for licensing of facilities of this nature:

(1) Is licensed pursuant to such law; or

(2) If not subject to licensure, is approved by the agency of the State or locality responsible for licensing skilled nursing facilities as meeting fully the standards established for such licensing, and

(3) Except that a facility which formerly met fully such licensure requirements, but is currently determined not to meet fully all such requirements, may be recognized for a period specified by the State standard-setting authority.

(b) *Standard: Licensure or registration of personnel.* Staff of the facility are licensed or registered in accordance with applicable laws.

(c) *Standard: Conformity with other Federal, State, and local laws.* The facility is in conformity with all Federal, State, and local laws relating to fire and safety, sanitation, communicable and reportable diseases, postmortem procedures, and other relevant health and safety requirements.

§ 405.1121 Conditions of participation—governing body and management.

The skilled nursing facility has an effective governing body, or designated persons so functioning, with full legal authority and responsibility for the operation of the facility. The governing body adopts and enforces rules and regulations relative to health care and safety of patients, to the protection of their personal and property rights, and to the general operation of the facility.

(a) *Standard: Disclosure of ownership.* The facility complies with the disclosure requirements of § 420.206 of this chapter.

(b) *Standard: Staffing patterns.* The facility furnishes to the State survey agency information from payroll records setting forth the average numbers and types of personnel (in full-time equivalents) on each tour of duty during at least 1 week of each quarter. Such week will be selected by the survey agency.

(c) *Standard: Bylaws.* The governing body adopts effective patient care policies and administrative policies and bylaws governing the operation of the facility, in accordance with legal requirements. Such policies and bylaws are in writing, dated, and made available to all members of the governing body which ensures that they are operational, and reviews and revises them as necessary.

(d) *Standard: Independent medical evaluation (medical review).* The governing body adopts policies to ensure that the facility cooperates in an effective program which provides for a regular program of independent medical evaluation and audit of the patients in the facility to the extent required by the programs in which the facility participates (including, at least annually, medical evaluation of each patient's need for skilled nursing facility care).

(e) *Standard: Administrator.* The governing body appoints a qualified administrator who is responsible for the overall management of the facility, enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights, and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the administrator maintains ongoing liaison among the governing body, medical and nursing staffs, and other professional and supervisory staff of the facility, and studies and acts upon recommendations made by the utilization review and other committees. In the absence of the administrator, an employee is authorized, in writing, to act on his behalf.

(f) *Standard: Institutional planning.* The skilled nursing facility, under the direction of the governing body, prepares an overall plan and budget which provides for an annual operating budget and a capital expenditure plan.

(1) *Annual operating budget.* There is an annual operating budget which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense).

(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period (including the year to which the operating budget described in paragraph (f)(1) of this section is applicable), which includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure in excess of $100,000 for items which would, under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $100,000, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expendi-

tures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions which are separated in time but are components of an overall plan or patient care objective are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of such financing is, in any part, the anticipated reimbursement from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Health Insurance for the Aged and Disabled) or title XIX (Grants to States for Medical Assistance Programs) of the Social Security Act, the plan states:

(*a*) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed pursuant to the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, to meet the need for adequate health care facilities in the area covered by the plan or plans so developed;

(*b*) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval pursuant to section 1122 of the Social Security Act (42 U.S.C. 1320a-1) and implementing regulations.

(*c*) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it has been so presented.

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the skilled nursing facility by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (or chief medical officer, or patient care policies advisory group as described in § 405.1122(a)) of the skilled nursing facility.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (f) (3) of this section under the direction of the governing body of the skilled nursing facility.

(g) *Standard: Personnel policies and procedures.* The governing body, through the administrator, is responsible for implementing and maintaining written personnel policies and procedures that support sound patient care and personnel practices. Personnel records are current and available for each employee and contain sufficient information to support placement in the position to which assigned. Written policies for control of communicable disease are in effect to ensure that employees with symptoms or signs of communicable disease or infected skin lesions are not permitted to work, and that a safe and sanitary environment for patients and personnel exists and incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Employees are provided, or referred for, periodic health examinations, to ensure freedom from communicable disease.

(h) *Standard: Staff development.* An ongoing educational program is planned and conducted for the development and improvement of skills of all the facility's personnel, including training related to problems and needs of the aged, ill, and disabled. Each employee receives appropriate orientation to the facility and its policies, and to his position and duties. Inservice training includes at least prevention and control of infections, fire prevention and safety, accident prevention, confidentiality of patient information, and preservation of patient dignity, including protection of his privacy and personal and property rights. Records are maintained which indicate the content of, and attendance at, such staff development programs.

(i) *Standard: Use of outside resources.* If the facility does not employ a qualified professional person to render a specific service to be provided by the facility, it makes arrangements to have such a service provided by an outside resource—a person or agency that will render direct service to patients or act as a consultant to the facility. The responsibilities, functions, and objectives, and the terms of agreement, including financial arrangements and charges, of each such outside resource are delineated in writing and signed by an authorized representative of the facility and the person or agency providing the service. Agreements pertaining to services must specify that the facility assumes professional and administrative responsibility for the services rendered. The outside resource, when acting as a consultant, appraises the administrator of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the administrator for followup action and evaluation of performance. (See requirement under each service—§§ 405.1125 through 405.1132.)

(j) *Standard: Notification of changes in patient status.* The facility has appropriate written policies and procedures relating to notification of the patient's attending physician and other responsible persons in the event of an accident involving the patient, or other significant change in the patient's physical, mental, or emotional status, or patient charges, billings, and related administrative matters. Except in a medical emergency, a patient is not transferred or discharged, nor is treatment altered radically, without consultation with the patient or, if he is incompetent, without prior notification of next of kin or sponsor.

(k) *Standard: Patients' rights.* The governing body of the facility establishes written policies regarding the rights and responsibilities of patients and, through the administrator, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients, to any guardians, next of kin, sponsoring agency(ies), or representative payees selected pursuant to section 205 (j) of the Social Security Act, and Subpart Q of 20 CFR Part 404, and to the public. The staff of the facility is trained and involved in the implementation of these policies and procedures. These patients' rights policies and procedures ensure that, at least, each patient admitted to the facility:

(1) Is fully informed, as evidenced by the patient's written acknowledgment, prior to or at the time of admission and during stay, of these rights and of all rules and regulations governing patient conduct and responsibilities;

(2) Is fully informed, prior to or at the time of admission and during stay, of services available in the facility, and of related charges including any charges for services not covered under titles XVIII or XIX of the Social Security Act, or not covered by the facility's basic per diem rate;

(3) Is fully informed, by a physician, of his medical condition unless medically contraindicated (as documented, by a physician, in his medical record), and is afforded the opportunity to participate in the planning of his medical treatment and to refuse to participate in experimental research;

(4) Is transferred or discharged only for medical reasons, or for his welfare or that of other patients, or for nonpayment of his stay (except as prohibited by titles XVIII or XIX of the Social Security Act), and is given reasonable advance notice to ensure orderly transfer or discharge, and such actions are documented in his medical record;

(5) Is encouraged and assisted, throughout his period of stay, to exercise his rights as a patient and as a citizen, and to this end may voice grievances and recommend changes in policies and services to facility staff and/or to outside representatives of his choice, free from restraint, interference, coercion, discrimination, or reprisal;

(6) May manage his personal financial affairs, or is given at least a quarterly accounting of financial transactions made on his behalf should the facility accept his written delegation of this responsibility to the facility for any period of time in conformance with State law;

(7) Is free from mental and physical abuse, and free from chemical and (except in emergencies) physical restraints except as authorized in writing by a physician for a specified and limited period of time, or when neces-

sary to protect the patient from injury to himself or to others;

(8) Is assured confidential treatment of his personal and medical records, and may approve or refuse their release to any individual outside the facility, except, in case of his transfer to another health care institution, or as required by law or third-party payment contract;

(9) Is treated with consideration, respect, and full recognition of his dignity and individuality, including privacy in treatment and in care for his personal needs;

(10) Is not required to perform services for the facility that are not included for therapeutic purposes in his plan of care;

(11) May associate and communicate privately with persons of his choice, and send and receive his personal mail unopened, unless medically contraindicated (as documented by his physician in his medical record);

(12) May meet with, and participate in activities of, social, religious, and community groups at his discretion, unless medically contraindicated (as documented by his physician in his medical record);

(13) May retain and use his personal clothing and possessions as space permits, unless to do so would infringe upon rights of other patients, and unless medically contraindicated (as documented by his physician in his medical record); and

(14) If married, is assured privacy for visits by his/her spouse; if both are inpatients in the facility, they are permitted to share a room, unless medically contraindicated (as documented by the attending physician in the medical record).

All rights and responsibilities specified in paragraphs (k) (1) through (4) of this section—as they pertain to (i) a patient adjudicated incompetent in accordance with State law, (ii) a patient who is found, by his physician, to be medically incapable of understanding these rights, or (iii) a patient who exhibits a communication barrier—devolve to such patient's guardian, next of kin, sponsoring agency(ies), or representative payee (except when the facility itself is representative payee) selected pursuant to section 205(j) of the Social Security Act and Subpart Q of 20 CFR Part 404.

(l) *Standard: Patient care policies.* The skilled nursing facility has written patient care policies to govern the continuing skilled nursing care and related medical or other services provided.

(1) The facility has policies, which are developed by the medical director or the organized medical staff (see § 405.1122), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel including one or more physicians and one or more registered nurses, to govern the skilled nursing care and related medical or other services it provides. The policies, which are available to admitting physicians, sponsoring agencies, patients, and the public, reflect awareness of, and provision for, meeting the total medical and psychosocial needs of patients, including admission, transfer, and discharge planning; and the range of services available to patients, including frequency of physician visits by each category of patients admitted. These policies also include provisions to protect patients' personal and property rights. Medical records and minutes of staff and committee meetings reflect that patient care is being rendered in accordance with the written patient care policies, and that utilization review committee recommendations regarding the policies are reviewed and necessary steps taken to ensure compliance.

(2) The medical director or a registered nurse is designated, in writing, to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated to a registered nurse, the medical director serves as the advisory physician from whom she receives medical guidance. (See § 405.1122(b).)

(m) *Standard: Protection of patients' funds.* The facility establishes and maintains a system that—

(1) Ensures full and complete accounting of its patients' personal funds; and

(2) Precludes commingling of a patient's funds with funds of the facility

or of any person other than another patient.

[39 FR 2240, Jan. 17, 1974, as amended at 39 FR 35775, Oct. 3, 1974; 40 FR 24325, June 5, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 44 FR 41642, July 17, 1979; 50 FR 33031, Aug. 16, 1985]

§ 405.1122 Condition of participation—medical direction.

The facility retains, effective not later than 12 full calendar months from December 2, 1974, pursuant to a written agreement, a physician, licensed under State law to practice medicine or osteopathy, to serve as medical director on a part-time or full-time basis as is appropriate for the needs of the patients and the facility. If the facility has an organized medical staff, the medical director is designated by the medical staff with approval of the governing body. A medical director may be designated for a single facility or multiple facilities through arrangements with a group of physicians, a local medical society, a hospital medical staff, or through another similar arrangement. The medical director is responsible for the overall coordination of the medical care in the facility to ensure the adequacy and appropriateness of the medical services provided to patients and to maintain surveillance of the health status of employees. (See § 405.1911(b) regarding waiver of the requirement for a medical director.)

(a) *Standard: Coordination of medical care.* Medical direction and coordination of medical care in the facility are provided by a medical director. The medical director is responsible for the development of written bylaws, rules, and regulations which are approved by the governing body and include delineation of the responsibilities of attending physicians. Coordination of medical care includes liaison with attending physicians to ensure their writing orders promptly upon admission of a patient, and periodic evaluation of the adequacy and appropriateness of health professional and supportive staff and services.

(b) *Standard: Responsibilities to the facility.* The medical director is responsible for surveillance of the health status of the facility's employees. Incidents and accidents that occur on the premises are reviewed by the medical director to identify hazards to health and safety. The administrator is given appropriate information to help ensure a safe and sanitary environment for patients and personnel. The medical director is responsible for the execution of patient care policies in accordance with § 405.1121(l).

[39 FR 35776, Oct. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.1123 Condition of participation—physician services.

Patients in need of skilled nursing or rehabilitative care are admitted to the facility only upon the recommendation of, and remain under the care of, a physician. To the extent feasible, each patient or his sponsor designates a personal physician.

(a) *Standard: Medical findings and physicians' orders at time of admission.* There is made available to the facility, prior to or at the time of admission, patient information which includes current medical findings, diagnoses, and orders from a physician for immediate care of the patient. Information about the rehabilitation potential of the patient and a summary of prior treatment are made available to the facility at the time of admission or within 48 hours thereafter.

(b) *Standard: Patient supervision by physician.* The facility has a policy that the health care of every patient must be under the supervision of a physician who, based on a medical evaluation of the patient's immediate and long-term needs, prescribes a planned regimen of total patient care. Each attending physician is required to make arrangements for the medical care of his patients in his absence. The medical evaluation of the patient is based on a physical examination done within 48 hours of admission unless such examination was performed within 5 days prior to admission. The patient is seen by his attending physician at least once every 30 days for the first 90 days following admission. The patient's total program of care (including medications and treatments) is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days, and revised as necessary. A progress note is written and signed by the physician at the time of each visit, and he signs all his orders. Subsequent to the 90th day following admission, an alternate schedule for physician visits may be adopted where the attending physician determines and so justifies in the patient's medical record that the patient's condition does not necessitate visits at 30-day intervals. This alternate schedule does not apply for patients who require specialized rehabilitative services, in which case the review must be in accordance with § 405.1126(b). At no time may the alternate schedule exceed 60 days between visits. If the physician decides upon an alternate schedule of visits of more than 30 days for a patient, (1) in the case of a Medicaid benefits recipient, the facility notifies the State Medicaid agency of the change in schedule, including justification, and (2) the utilization review committee or the medical review team (see § 405.1121(d)) promptly reevaluates the patient's need for monthly physician visits as well as his continued need for skilled nursing facility services (see § 405.1137(d)). If the utilization review committee or the medical review team does not concur in the schedule of visits at intervals of more than 30 days, the alternate schedule is not acceptable.

(c) *Standard: Availability of physicians for emergency patient care.* The facility has written procedures, available at each nurses station, that provide for having a physician available to furnish necessary medical care in case of emergency.

§ 405.1124 Condition of participation—nursing services.

The skilled nursing facility provides 24-hour service by licensed nurses, including the services of a registered nurse at least during the day tour of duty 7 days a week. There is an organized nursing service with a sufficient number of qualified nursing personnel to meet the total nursing needs of all patients in the facility. (See § 405.1911(a) regarding waiver of the 7-day registered nurse requirement.)

(a) *Standard: Director of nursing services.* The director of nursing services is a qualified registered nurse employed full-time who has, in writing, administrative authority, responsibility, and accountability for the functions, activities, and training of the nursing services staff, and serves only one facility in this capacity. If the director of nursing services has other institutional responsibilities, a qualified registered nurse serves as her assistant so that there is the equivalent of a full-time director of nursing services on duty. The director of nursing services is responsible for the development and maintenance of nursing service objectives, standards of nursing practice, nursing policy and procedure manuals, written job descriptions for each level of nursing personnel, scheduling of daily rounds to see all patients, methods for coordination of nursing services with other patient services, for recommending the number and levels of nursing personnel to be employed, and nursing staff development (see § 405.1121(h)).

(b) *Standard: Charge nurse.* A registered nurse, or a qualified licensed practical (vocational) nurse, is designated as charge nurse by the director of nursing services for each tour of duty, and is responsible for supervision of the total nursing activities in the facility during each tour of duty. The director of nursing services does not serve as charge nurse in a facility with an average daily total occupancy of 60 or more patients. The charge nurse delegates responsibility to nursing personnel for the direct nursing care of specific patients during each tour of duty, on the basis of staff qualifications, size and physical layout of the facility, characteristics of the patient load, and the emotional, social, and nursing care needs of patients.

(c) *Standard: Twenty-four-hour nursing service.* The facility provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient care policies developed as provided in § 405.1121(l). The policies are designed to ensure that each patient receives treatments, medications, and diet as prescribed, and rehabilitative nursing care as needed; receives proper care to prevent decubitus ulcers and deformities, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection, and encouraged, assisted, and trained in self-care and group activities. Nursing personnel, including at least one registered nurse on the day tour of duty 7 days a week, licensed practical (vocational) nurses, nurse aides, orderlies, and ward clerks, are assigned duties consistent with their education and experience and based on the characteristics of the patient load. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel, including relief personnel, who worked on each unit for each tour of duty.

(d) *Standard: Patient care plan.* In coordination with the other patient care services to be provided, a written patient care plan for each patient is developed and maintained by the nursing service consonant with the attending physician's plan of medical care, and is implemented upon admission. The plan indicates care to be given and goals to be accomplished and which professional service is responsible for each element of care. The patient care plan is reviewed, evaluated, and updated as necessary by all professional personnel involved in the care of the patient.

(e) *Standard: Rehabilitative nursing care.* Nursing personnel are trained in rehabilitative nursing, and the facility has an active program of rehabilitative nursing care which is an integral part of nursing service and is directed toward assisting each patient to achieve and maintain an optimal level of self-care and independence. Rehabilitative nursing care services are performed daily for those patients who require such service, and are recorded routinely.

(f) *Standard: Supervision of patient nutrition.* Nursing personnel are aware of the nutritional needs and food and fluid intake of patients and assist promptly where necessary in the feeding of patients. A procedure is established to inform the dietetic service of physicians' diet orders and of patients' dietetic problems. Food and fluid intake of patients is observed, and deviations from normal are recorded and reported to the charge nurse and the physician.

(g) *Standard: Administration of drugs.* Drugs and biologicals are administered only by physicians, licensed nursing personnel, or by other personnel who have completed a State-approved training program in medication administration. Procedures are established by the pharmaceutical services committee (see § 405.1127(d)) to ensure that drugs to be administered are checked against physicians' orders, that the patient is identified prior to administration of a drug, and that each patient has an individual medication record and that the dose of drug administered to that patient is properly recorded therein by the person who administered the drug. Drugs and biologicals are administered as soon as possible after doses are prepared, and are administered by the same person who prepared the doses for administration, except under single unit dose package distribution systems. (See § 405.1101(h).)

(h) *Standard: Conformance with physicians' drug orders.* Drugs are administered in accordance with written orders of the attending physician. Drugs not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies. Physicians' verbal orders for drugs are given only to a licensed nurse, pharmacist, or physician and are immediately recorded and signed by the person receiving the order. (Verbal orders for Schedule II drugs are permitted only in the case of a bona fide emergency situation.) Such orders are countersigned by the attending physician within 48 hours. The attending physician is notified of an automatic stop order prior to the last dose so that he may decide if the administration of the drug or biological is to be continued or altered.

(i) *Standard: Storage of drugs and biologicals.* Procedures for storing and disposing of drugs and biologicals are established by the pharmaceutical services committee. In accordance with State and Federal laws, all drugs and biologicals, are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked, permanently affixed compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit approved by the pharmaceutical services committee is kept readily available.

[39 FR 2240, Jan. 17, 1974, as amended at 39 FR 35776, Oct. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.1125 Condition of participation—dietetic services.

The skilled nursing facility provides a hygienic dietetic service that meets the daily nutritional needs of patients, ensures that special dietary needs are met, and provides palatable and attractive meals. A facility that has a contract with an outside food management company may be found to be in compliance with this condition provided the facility and/or company meets the standards listed herein.

(a) *Standard: Staffing.* Overall supervisory responsibility for the dietetic service is assigned to a full-time qualified dietetic service supervisor. If the dietetic service supervisor is not a qualified dietitian he functions with frequent, regularly scheduled consultation from a person so qualified. (See § 405.1121(i).) In addition, the facility employs sufficient supportive personnel competent to carry out the functions of the dietetic service. Food service personnel are on duty daily over a period of 12 or more hours. If consultant dietetic services are used, the consultant's visits are at appropriate times, and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, patient counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus, and participation in development or revision of dietetic policies and procedures and in planning and conducting inservice education programs (see § 405.1121(h)).

(b) *Standard: Menus and nutritional adequacy.* Menus are planned and followed to meet nutritional needs of patients in accordance with physicians' orders and, to the extent medically possible, in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council National Academy of Sciences.

(c) *Standard: Therapeutic diets.* Therapeutic diets are prescribed by the attending physician. Therapeutic menus are planned in writing, and prepared and served as ordered, with supervision or consultation from the dietitian and advice from the physician whenever necessary. A current therapeutic diet manual approved by the dietition is readily available to attending physicians and nursing and dietetic service personnel.

(d) *Standard: Frequency of meals.* At least three meals or their equivalent are served daily, at regular hours, with not more than a 14-hour span between substantial evening meal and breakfast. To the extent medically possible, bedtime nourishments are offered routinely to all patients.

(e) *Standard: Preparation and service of food.* Foods are prepared by methods that conserve nutritive value, flavor, and appearance, and are attractively served at the proper temperatures and in a form to meet individual needs. If a patient refuses food served, appropriate substitutes of similar nutritive value are offered.

(f) *Standard: Hygiene of staff.* Dietetic service personnel are free of communicable diseases and practice hygienic food-handling techniques. In the event food service employees are assigned duties outside the dietetic service, these duties do not interfere with the sanitation, safety, or time required for dietetic work assignments. (See § 405.1121(g).)

(g) *Standard: Sanitary conditions.* Food is procured from sources approved or considered satisfactory by Federal, State, or local authorities, and stored, prepared, distributed, and served under sanitary conditions. Waste is disposed of properly. Written reports of inspections by State and local health authorities are on file at the facility, with notation made of action taken by the facility to comply with any recommendations.

§ 405.1126 Condition of participation—specialized rehabilitative services.

In addition to rehabilitative nursing (§ 405.1124(e), the skilled nursing facility provides, or arranges for, under written agreement, specialized rehabilitative services by qualified personnel (i.e., physical therapy, speech pathology and audiology, and occupational therapy) as needed by patients to improve and maintain functioning. These services are provided upon the written order of the patient's attending physician. Safe and adequate space and equipment are available, commensurate with the services offered. If the facility does not offer such services directly, it does not admit nor retain patients in need of this care unless provision is made for such services under arrangement with qualified outside resources under which the facility assumes professional responsibilities for the services rendered. (See § 450.1121(i).)

(a) *Standard: Organization and staffing.* Specialized rehabilitative services are provided, in accordance with accepted professional practices, by qualified therapists or by qualified assistants or other supportive personnel under the supervision of qualified therapists. Other rehabilitative services also may be provided, but must be in a facility where all rehabilitative services are provided through an organized rehabilitative service under the supervision of a physician qualified in physical medicine who determines the goals and limitations of these services and assigns duties appropriate to the training and experience of those providing such services. Written administrative and patient care policies and procedures are developed for rehabilitative services by appropriate therapists and representatives of the medical, administrative, and nursing staffs.

(b) *Standard: Plan of care.* Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapist(s) and the nursing service. Therapy is provided only upon written orders of the attending physician. A report of the patient's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. The patient's progress is thereafter reviewed regularly, and the plan of rehabilitative care is reevaluated as necessary, but at least every 30 days, by the physician and the therapist(s).

(c) *Standard: Documentation of services.* The physician's orders, the plan of rehabilitative care, services rendered, evaluations of progress, and other pertinent information are recorded in the patient's medical record, and are dated and signed by the physician ordering the service and the person who provided the service.

(d) *Standard: Qualifying to provide outpatient physical therapy services.* If the facility provides outpatient physical therapy services, it meets the applicable health and safety regulations pertaining to such services as are included in Subpart Q of this part. (See §§ 405.1719; 405.1720; 405.1722(a) and (b)(1), (2), (3)(i), (4), (5), (6), (7), and (8); and 405.1725.)

[39 FR 2240, Jan. 17, 1974, as amended at 39 FR 35777, Oct. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.1127 Condition of participation—pharmaceutical services.

The skilled nursing facility provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility is responsible for providing such drugs and biologicals for its patients, insofar as they are covered under the programs, and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate Federal, State, and local laws. (See § 405.1124(g), (h), and (i).)

(a) *Standard: Supervision of services.* The pharmaceutical services are under the general supervision of a qualified pharmacist who is responsible to the administrative staff for developing, coordinating, and supervising all pharmaceutical services. The pharmacist (if not a full-time employee) de votes a sufficient number of hours, based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities. The pharmacist reviews the drug regimen of each patient at least monthly, and reports any irregularities to the medical director and administrator. The pharmacists submits a written report at least quarterly to the pharmaceutical services committee on the status of the facility's pharmaceutical service and staff performance.

(b) *Standard: Control and accountability.* The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility. Only approved drugs and biologicals are used in the facility, and are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

(c) *Standard: Labeling of drugs and biologicals.* The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

(d) *Standard: Pharmaceutical services committee.* A pharmaceutical services committee (or its equivalent) develops written policies and procedures for safe and effective drug therapy, distribution, control, and use. The committee is comprised of at least the pharmacist, the director of nursing services, the administrator, and one physician. The committee oversees pharmaceutical service in the facility, makes recommendations for improvement, and monitors the service to ensure its accuracy and adequacy. The committee meets at least quarterly and documents its activities, findings, and recommendations.

§ 405.1128 Condition of participation—laboratory and radiologic services.

The skilled nursing facility has provision for promptly obtaining required laboratory, X-ray, and other diagnostic services.

(a) *Standard: Provision for services.* If the facility provides its own laboratory and X-ray services, these meet the applicable conditions established for certification of hospitals that are contained in §§ 482.26 and 482.27 of this chapter, respectively. If the facility itself does not provide such services, arrangements are made for obtaining these services from a physician's office, a participating hospital or skilled nursing facility, or a portable X-ray supplier or independent laboratory which is approved to provide these services under the program. All such services are provided only on the orders of the attending physician, who is notified promptly of the findings. The facility assists the patient, if necessary, in arranging for transportation to and from the source of service. Signed and dated reports of a clinical laboratory, X-ray, and other diagnostic services are filed with the patient's medical record.

(b) *Standard: Blood and blood products.* Blood handling and storage facilities are safe, adequate, and properly supervised. If the facility provides for maintaining and transfusing blood and blood products, it meets the conditions established for certification of hospitals that are contained in § 482.27(d) of this chapter. If the facility does not provide its own facilities but does provide transfusion services alone, it meets at least the requirements of § 482.27(d)(1), (2), (3), and (6) of this chapter.

[39 FR 2240, Jan. 17, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 22040, June 17, 1986]

§ 405.1129 Condition of participation—dental services.

The skilled nursing facility has satisfactory arrangements to assist patients to obtain routine and emergency dental care (See § 405.1121(i).) (The basic Hospital Insurance Program does not cover the services of a dentist in a skilled nursing facility in connection with the care, treatment, filling, removal, or replacement of teeth or structures supporting the teeth; and only certain oral surgery is included in the Supplemental Medical Insurance Program.)

(a) *Standard: Advisory dentist.* An advisory dentist participates in the staff development program for nursing and other appropriate personnel (see § 405.1121(h)), and recommends oral hygiene policies and practices for the care of patients.

(b) *Standard: Arrangements for outside services.* The facility has a cooperative agreement with a dental service, and maintains a list of dentists in the community for patients who do not have a private dentist. The facility assists the patient, if necessary, in arranging for transportation to and from the dentist's office.

§ 405.1130 Condition of participation—social services.

The skilled nursing facility has satisfactory arrangements for identifying the medically related social and emotional needs of the patient. It is not mandatory that the skilled nursing facility itself provide social services in order to participate in the program. If the facility does not provide social services, it has written procedures for referring patients in need of social services to appropriate social agencies. If social services are offered by the facility, they are provided under a clearly defined plan, by qualified persons, to assist each patient to adjust to the social and emotional aspects of his illness, treatment, and stay in the facility.

(a) *Standard: Social service functions.* The medically related social and emotional needs of the patient are identified and services provided to meet them, either by qualified staff of the facility, or by referral, based on established procedures, to appropriate social agencies. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency. The patient and his family or responsible person are fully informed of the patient's personal and property rights.

(b) *Standard: Staffing.* If the facility offers social services, a member of the staff of the facility is designated as responsible for social services. If the designated person is not a qualified social worker, the facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance on a regularly scheduled basis. (See § 405.1121(i).) The social service also has sufficient supportive personnel to meet patient needs. Facilities are adequate for social service personnel, easily accessible to patients and medical and other staff, and ensure privacy for interviews.

(c) *Standard: Records and confidentiality of social data.* Records of pertinent social data about personal and family problems medically related to the patient's illness and care, and of action taken to meet his needs, are maintained in the patient's medical record. If social services are provided by an outside resource, a record is maintained of each referral to such resource. Policies and procedures are established for ensuring the confidentiality of all patients' social information.

§ 405.1131 Condition of participation—patient activities.

The skilled nursing facility provides for an activities program, appropriate to the needs and interests of each patient, to encourage self care, resumption of normal activities, and maintenance of an optimal level of psychosocial functioning.

(a) *Standard: Responsibility for patient activities.* A member of the facility's staff is designated as responsible for the patient activities program. If he is not a qualified patient activities coordinator, he functions with frequent, regularly scheduled consultation from a person so qualified. (See § 405.1121(i).)

(b) *Standard: Patient activities program.* Provision is made for an ongoing program of meaningful activities appropriate to the needs and interests of patients, designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any. Each patient's activities program is approved by the patient's attending physician as not in conflict with the treatment plan. The activities are designed to promote the physical, social, and mental well-being of the patients. The facility makes available adequate space and a variety of supplies and equipment to satisfy the individual interests of patients (see § 405.1134(g)).

§ 405.1132 Condition of participation—medical records.

The facility maintains clinical (medical) records on all patients in accordance with accepted professional standards and practices. The medical record service has sufficient staff, facilities, and equipment to provide medical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Staffing.* Overall supervisory responsibility for the medical record service is assigned to a full-time employee of the facility. The facility also employs sufficient supportive personnel competent to carry out the functions of the medical record service. If the medical record supervisor is not a qualified medical record practictioner, this person functions with consultation from a person so qualified. (See § 405.1121(i).)

(b) *Standard: Protection of medical record information.* The facility safeguards medical record information against loss, destruction, or unauthorized use.

(c) *Standard: Content.* The medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of data: Documented evidence of assessment of the needs of the patient, of establishment of an appropriate plan of treatment, and of the care and services provided; authentication of hospital diagnoses (discharge summary, report from patient's attending physician, or transfer form), identification data and consent forms, medical and nursing history of patient, report of physical examination(s), diagnostic and therapeutic orders, observations and progress notes, reports of treatments and clinical findings, and discharge summary including final diagnosis and prognosis.

(d) *Standard: Physician documentation.* Only physicians enter or authenticate in medical records opinions that require medical judgment (in accordance with medical staff bylaws, rules, and regulations, if applicable). Each physician signs his entries into the medical record.

(e) *Standard: Completion of records and centralization of reports.* Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient's stay is centralized in the patient's medical record.

(f) *Standard: Retention and preservation.* Medical records are retained for a period of time not less than that determined by the respective State statute, the statute of limitations in the State, or 5 years from the date of discharge in the absence of a State statute, or, in the case of a minor, 3 years after the patient becomes of age under State law.

(g) *Standard: Indexes.* Patients' medical records are indexed according to name of patient and final diagnoses to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(h) *Standard: Location and facilities.* The facility maintains adequate facilities and equipment, conveniently located, to provide efficient processing of medical records (reviewing, indexing, filing, and prompt retrieval).

§ 405.1133 Condition of participation—transfer agreement.

The skilled nursing facility has in effect a transfer agreement with one or more hospitals approved for participation under the programs, which provides the basis for effective working arrangements under which inpatient hospital care or other hospital services are available promptly to the facility's patients when needed. (A facility that has been unable to establish a transfer agreement with the hospital(s) in the community or service area after documented attempts to do so is considered to have such an agreement in effect.)

(a) *Standard: Patient transfer.* A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case the two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that:

(1) Transfer of patients will be effected between the hospital and the skilled nursing facility, ensuring timely admission, whenever such transfer is medically appropriate as determined by the attending physician, and

(2) There will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions, and

(3) Security and accountability for patients' personal effects are provided on transfer.

Any skilled nursing facility which does not have such agreement in effect, but which is found by a State agency (of the State in which such facility is situated) with which an agreement under section 1864 is in effect (or, in the case of a State in which no such agency has an agreement under 1864, by the Secretary) to have attempted in good faith to enter into such an agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and the information referred to in paragraph (a)(2) of this section, shall be considered to have such an agreement in effect if and for so long as such agency (or the Secretary, as the case may be) finds that to do so is in the public interest and essential to ensuring skilled nursing facility services for persons in the community who are eligible for payments with respect to such services under the programs.

§ 405.1134 Condition of participation—physical environment.

The skilled nursing facility is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public.

(a) *Standard: Life safety from fire.* Except as provided in paragraphs (a)(1) through (a)(3) of this section, the skilled nursing facility must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference).[1]

(1) A skilled nursing facility is considered to be in compliance with this standard as long as the facility—

(i) On November 26, 1982, complied, with or without waivers, with the requirements of the 1967 or 1973 editions of the Life Safety Code and continues to remain in compliance with those editions of the Code; or

(ii) On May 9, 1988, complied, with or without waivers, with the 1981 edition of the Life Safety Code and continues to remain in compliance with that edition of the Code.

(2) After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

(3) The provisions of the Life Safety Code do not apply in a State where HCFA finds, in accordance with applicable provisions of section 1861(j)(13) of the Social Security Act, that a fire and safety code, imposed by State law, adequately protects patients in skilled nursing facilities.

(4) Any facility of two or more stories that is not of fire resistive construction and is participating on the basis of a waiver of construction type or height, may not house blind, nonambulatory, or physically handi-

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[1] Incorporation of the 1985 edition of the National Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51 that govern the use of incorporations by reference. The Code is available for inspection at the Office of the Federal Register Information Center, Room 8401, 1100 L Street NW., Washington, D.C. Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, Mass. 02269. If any changes in this code are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.

capped patients above the street-level floor unless the facility—

(i) Is one of the following construction types (as defined in the Life Safety Code):

(A) Type II (1, 1, 1)—protected noncombustible.

(B) Fully sprinklered Type II (0, 0, 0)—non-combustible.

(C) Fully sprinklered Type III (2, 1, 1)—protected ordinary.

(D) Fully sprinklered Type V (1, 1, 1)—protected wood frame; or

(ii) Achieves a passing score on the Fire Safety Evaluation System (FSES).

(b) *Standard: Emergency power.* The facility provides an emergency source of electrical power necessary to protect the health and safety of patients in the event the normal electrical supply is interrupted. The emergency electrical power system must supply power adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life support systems. Where life support systems are used, emergency electrical service is provided by an emergency generator located on the premises.

(c) *Standard: Facilities for physically handicapped.* The facility is accessible to, and functional for, patients, personnel, and the public. All necessary accommodations are made to meet the needs of persons with semiambulatory disabilities, sight and hearing disabilities, disabilities of coordination, as well as other disabilities, in accordance with the American National Standards Institute (ANSI) Standard No. A117.1, American Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped. The Secretary (or in the case of a facility participating as a skilled nursing facility under title XIX only, the survey agency—see 42 CFR 449.33(a)(1)(i)) may waive in existing buildings, for such periods as deemed appropriate, specific provisions of ANSI Standard No. A117.1 which, if rigidly enforced, would result in unreasonable hardship upon the facility, but only if such waiver will not adversely affect the health and safety of patients.

(d) *Standard: Nursing unit.* Each nursing unit has at least the following basic service areas: Nurses station, storage and preparation area(s) for drugs and biologicals, and utility and storage rooms that are adequate in size, conveniently located, and well lighted to facilitate staff functioning. The nurses station is equipped to register patients' calls through a communication system from patient areas, including patient rooms and toilet and bathing facilities.

(e) *Standard: Patient rooms and toilet facilities.* Patient rooms are designed and equipped for adequate nursing care and the comfort and privacy of patients, and have no more than four beds, except in facilities primarily for the care of the mentally ill and/or retarded where there shall be no more than 12 beds per room. (An institution primarily engaged in the care of the mentally retarded or in the treatment of mental diseases cannot qualify as a participating skilled nursing facility under Medicare.) Single patient rooms measure at least 100 square feet, and multipatient rooms provide a minimum of 80 square feet per bed. The Secretary (or in the case of a facility participating as a skilled nursing facility under title XIX only, the survey agency—see 42 CFR 449.33(a)(1)(i)) may permit variations in individual cases where the facility demonstrates in writing that such variations are in accordance with the particular needs of the patients and will not adversely affect their health and safety. Each room is equipped with, or is conveniently located near, adequate toilet and bathing facilities. Each room has direct access to a corridor and outside exposure, with the floor at or above grade level.

(f) *Standard: Facilities for special care.* Provision is made for isolating patients as necessary in single rooms ventilated to the outside, with private toilet and handwashing facilities. Procedures in aseptic and isolation techniques are established in writing and followed by all personnel. Such areas are identified by appropriate precautionary signs.

(g) *Standard: Dining and patient activities rooms.* The facility provides one or more clean, orderly, and appropriately furnished rooms of adequate size designated for patient dining and for patient activities. These areas are well-lighted and well-ventilated. If a multipurpose room is used for dining and patient activities, there is sufficient space to accommodate all activities and prevent their interference with each other.

(h) *Standard: Kitchen and dietetic service areas.* The facility has kitchen and dietetic service areas adequate to meet food service needs. These areas are properly ventilated, and arranged and equipped for sanitary refrigeration, storage, preparation, and serving of food as well as for dish and utensil cleaning and refuse storage and removal.

(i) *Standard: Maintenance of equipment, building, and grounds.* The facility establishes a written preventive maintenance program to ensure that equipment is operative and that the interior and exterior of the building are clean and orderly. All essential mechanical, electrical, and patient care equipment is maintained in safe operating condition.

(j) *Standard: Other environmental considerations.* The facility provides a functional, sanitary, and comfortable environment for patients, personnel, and the public. Provision is made for adequate and comfortable lighting levels in all areas, limitation of sounds at comfort levels, maintaining a comfortable room temperature, procedures to ensure water to all essential areas in the event of loss of normal water supply, and adequate ventilation through windows or mechanical means or a combination of both. Corridors are equipped with firmly secured handrails on each side.

[39 FR 2240, Jan. 17, 1974, as amended at 39 FR 35777, Oct. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 11508, Apr. 7, 1988]

§ 405.1135 Condition of participation—infection control.

The skilled nursing facility establishes an infection control committee of representative professional staff with responsibility for overall infection control in the facility. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection control committee.* The infection control committee is composed of members of the medical and nursing staffs, administration, and the dietetic, pharmacy, housekeeping, maintenance, and other services. The committee establishes policies and procedures for investigating, controlling, and preventing infections in the facility, and monitors staff performance to ensure that the policies and procedures are executed.

(b) *Standard: Aseptic and isolation techniques.* Written effective procedures in aseptic and isolation techniques are followed by all personnel. Procedures are reviewed and revised annually for effectiveness and improvement.

(c) *Standard: Housekeeping.* The facility employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated responsible for the services and for supervision and training of personnel. Nursing personnel are not assigned housekeeping duties. A facility that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the facility and/or outside resource meets the requirements of the standard.

(d) *Standard: Linen.* The facility has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The facility is maintained free from insects and rodents through operation of a pest control program.

§ 405.1136 Condition of participation—disaster preparedness.

The skilled nursing facility has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

(a) *Standard: Disaster plan.* The facility has an acceptable written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes procedures for prompt transfer of casualties and records, instructions regarding the location and use of alarm systems and signals and of firefighting equipment, information regarding methods of containing fire, procedures for notification of appropriate persons, and specifications of evacuation routes and procedures. (See § 405.1134(a).)

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his specific role in case of a disaster. (See § 405.1121(h).)

§ 405.1137 Condition of participation—utilization review.

The skilled nursing facility carries out utilization review of the services provided in the facility at least to inpatients who are entitled to benefits under the program(s). Utilization review has as its overall objectives both the maintenance of high quality patient care and assurance of appropriate and efficient utilization of facility services. There are two elements to utilization review: medical care evaluation studies that identify and examine patterns of care provided in the facility, and review of extended duration cases which is concerned with efficiency, appropriateness, and cost effectiveness of care.

(a) *Standard: Written plan of utilization review activity.* The skilled nursing facility has a currently applicable written description of its utilization review plan. Such description includes:

(1) The organization and composition of the committee or group which will be responsible for the utilization review function;

(2) Frequency of meetings;

(3) The type of records to be kept;

(4) The methods and criteria (including norms where available) to be used to define periods of continuous extended duration and to assign or select subsequent dates for continued stay review;

(5) Methods for selection and conduct of medical care evaluation studies;

(6) The relationship of the utilization review plan to claims administration by a third party;

(7) Arrangements for committee reports and their dissemination;

(8) Responsibilities of the skilled nursing facility's administrative staff.

(b) *Standard: Composition and organization of utilization review committee.* (1) The utilization review function is conducted by a staff committee of the skilled nursing facility composed of two or more physicians, with participation of other professional personnel, or by a group outside the facility which is similarly composed and which is established by the local medical or osteopathic society and some or all of the hospitals and skilled nursing facilities in the locality, or by a group established and organized in a manner approved by the Secretary that is capable of performing such function.

(2) The medical care evaluation studies, as described in paragraph (c) of this section, and educational duties of the review program, and the review of admissions and long-stay cases need not be performed by the same committee or group and they need not be performed by a specially established group.

(3) Review by the committee or group may not be conducted by any person who is employed by or who is financially interested in any skilled nursing facility or by any person who was professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Medical care evaluation studies.* Medical care evaluation studies are performed to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care. Studies emphasize identification and analysis of patterns of patient care, and suggest, where appropriate, possible changes for maintaining consistently high quality patient care and effective and efficient use of services. Each medical care evaluation study (whether medical or administrative in emphasis) identifies and analyzes factors related to the patient care rendered in the facility, and where indicated, results in recommendations for change beneficial to patients, staff, the facility and the community. Studies on a sample or other basis include, but need not be limited to: admissions, durations of stay, ancillary services furnished (including drugs and biologicals), and professional services performed on facility premises. At least one study must be in progress at any given time, and at least one study must be completed each year. The study will be accomplished by considering and analyzing data obtained from any one or a combination of the following sources:

(1) Medical records or other appropriate data;

(2) External organizations which compile statistics, design profiles, and produce other comparative data; and

(3) By cooperative endeavor with the PSRO, fiscal intermediary(ies), providers of services, or appropriate agencies.

The committee or group shall document the results of each medical care evaluation study and how such results have, where appropriate, been used to institute changes to improve the quality of care and promote more effective and efficient use of facilities and services.

(d) *Standard: Extended stay review.* (1) Periodic review is made of each current inpatient skilled nursing facility beneficiary case of continuous extended duration, the length of which is defined in the utilization review plan, to determine whether further inpatient stay is necessary. The plan may specify a different number of days for different diagnostic classes of cases, or may use the same number of days for all cases. In any event the period(s) specified bears a reasonable relationship to current average length-of-stay statistics and does not exceed 30 days after admission. An exception to this 30-day limit may be made where the extended stay review date is based on:

(i) The average, or some other appropriate point (e.g., median) of current length of stay data for diagnostic classes of cases selected by the committee or group in accordance with guidelines established by the Secretary, when the average (or other length of stay review point) for the individual's specific diagnostic class or category, based on functional capability, exceeds 30 days; or

(ii) A period, established pursuant to section 1814(h)(1) of the Act, which exceeds 30 days.

(2) The initial extended stay review takes place prior to or at the end of the period of extended duration specified pursuant to paragraph (d)(1) of this section. The review is based on the attending physician's reasons for and plan for continued stay and any other documentation the committee or group deems appropriate. Cases may be screened by a qualified nonphysician representative of the committee or group who uses criteria established by the physician members of the committee, provided that cases are referred to a physician member for further review when it appears that the patient no longer requires further inpatient care. Where the committee or group selects a nonphysician representative to screen extended stay review cases, it will select an individual with experience in such screening or appropriate training in the application of the screening criteria used, or both. The Secretary may grant an additional period of time, beyond July 1, 1975, the effective date of this paragraph, for a committee or group of a skilled nursing facility to select or develop the written criteria and standards required by this paragraph:

(i) Where the committee or group documents that it made every effort to comply by July 1, 1975, and that it is currently making substantial progress in developing the criteria and standards; and (ii) where the committee or group establishes a timetable for meeting the requirements which is acceptable to the Secretary.

(3) Where a finding is made that the individual continues to need inpatient skilled nursing care, an additional stay is approved for a period the committee or group deems appropriate, provided that reviews are made at least every 30 days for the first 90 days and at least every 90 days thereafter. Before the expiration of each new period, the case must be reviewed again in like manner, with such reviews being repeated as long as the stay continues beyond the scheduled review dates and notice has not been given pursuant to paragraph (e) of this section.

(e) *Standards: Admission or further stay not medically necessary.* (1) A final determination of the committee or group that an admission or continued stay is not medically necessary is made by at least two physician members of the committee or group, except that the final determination may be made by one physician member where the attending physician, when given an opportunity to express his views, does not do so, or does not contest the finding that the admission or continued stay is not medically necessary. (See § 405.166 regarding the restriction on payment after an adverse decision by the committee or group.)

(2) If the committee or group, or its nonphysician representative where a physician member concurs, has reason to believe from the review of an admission or an extended duration case or a case reviewed as part of a medical care evaluation study that further stay is no longer medically necessary (or that admissions were not medically necessary), the committee or group shall notify the individual's attending physician and afford him an opportunity to present his views before it makes a final determination. If the final determination of the committee or group is that further stay is no longer medically necessary, written notification of the finding is given to the facility, the attending physician, and the individual (or where appropriate, his next of kin) no later than two days after such final determination is made and, in no event in the case of an extended duration case, later than 3 working days after the end of the extended duration period specified pursuant to paragraph (d) of this section.

(f) *Standard: Administrative responsibilities.* The administrative staff of the facility is kept directly and fully informed of committee activities to facilitate support and assistance. The administrator studies and acts upon recommendations made by the committee, coordinating such functions with appropriate staff members.

(g) *Standard: Utilization review records.* Written records of committee activities are maintained. Appropriate reports, signed by the committee chairman, are made regularly to the medical staff, administrative staff, governing body, and sponsors (if any). Minutes of each committee meeting are maintained and include at least:

(1) Name of committee,

(2) Date and duration of meeting,

(3) Names of committee members present and absent,

(4) Description of activities presently in progress to satisfy the requirements for medical care evaluation studies, including the subject and reason for study, dates of commencement and expected completion, summary of studies completed since the last meeting, conclusions, and followup on implementation of recommendations made from previous studies, and

(5) Summary of extended duration cases reviewed, including the number of cases, case identification numbers, admission and review dates, and decisions reached, including the basis for each determination and action taken for each case not approved for extended care.

(h) *Standard: Discharge planning.* The facility maintains a centralized, coordinated program to ensure that each patient has a planned program of continuing care which meets his post-discharge needs.

(1) The facility has in operation an organized discharge planning program. The utilization review committee, in its evaluation of the current status of each extended duration case, has available to it the results of such discharge planning and information on alternative available community resources to which the patient may be referred.

(2) The administrator delegates responsibility for discharge planning, in writing, to one or more members of

the facility's staff, with consultation, if necessary, or arranges for this service to be provided by a health, social, or welfare agency (see § 405.1121(i)).

(3) The facility maintains written discharge planning procedures which describe (i) how the discharge coordinator will function, and his authority and relationships with the facility's staff; (ii) the time period in which each patient's need for discharge planning is determined (preferably within 7 days after the day of admission); (iii) the maximum time period after which a reevaluation of each patient's discharge plan is made; (iv) local resources available to the facility, the patient, and the attending physician to assist in developing and implementing individual discharge plans; and (v) provisions for periodic review and reevaluation of the facility's discharge planning program.

(4) At the time of discharge, the facility provides those responsible for the patient's postdischarge care with an appropriate summary of information about the discharged patient to ensure the optimal continuity of care. The discharge summary includes at least current information relative to diagnoses, rehabilitation potential, a summary of the course of prior treatment, physician orders for the immediate care of the patient, and pertinent social information.

(i) *Standard: Applicability of utilization review requirements approved under title XIX.* Notwithstanding the preceding paragraphs of this section, if the Secretary determines that the utilization review procedures established by a State pursuant to title XIX of the Social Security Act are superior in their effectiveness to the procedures required under this section, any provision of the State plan for which the waiver of the requirements set forth in this section for utilization review in skilled nursing facilities is granted shall, to the extent deemed appropriate by the Secretary, be utilized by skilled nursing facilities in that State, instead of the procedures specified in this section.

(j) *Correlation of PSRO review-Medicare utilization review activities.* Review activities under section 1158(a) of the Act shall be in lieu of the requirements of this section if a Professional Standards Review Organization (PSRO) has assumed review responsibility in accordance with the applicable provisions of Part 463 of this chapter for services provided by or in the facility to inpatients who are entitled to benefits under this Part 405. (See §§ 463.25, 463.26, and 463.28 for provisions concerning the correlation of functions under title XI-B and XVIII of the Act.)

[39 FR 2240, Jan. 17, 1974, as amended at 39 FR 35777, Oct. 3, 1974; 39 FR 41607, Nov. 29, 1974; 40 FR 14592, Apr. 1, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 44 FR 16398, Mar. 19, 1979]

Subpart L—Conditions of Participation; Home Health Agencies

AUTHORITY: Secs. 1102, 1842, 1861, 1862, 1870 and 1871 of the Social Security Act; 42 U.S.C. 1302, 1395u, 1395x, 1395y, 1395gg, and 1395hh.

SOURCE: 38 FR 18978, July 16, 1973, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1201 General.

(a) In order to participate as a home health agency in the health insurance program for the aged, an institution must be a "home health agency" within the meaning of section 1861(o) of the Social Security Act. This section of the law states a number of specific requirements which must be met by participating home health agencies and authorizes the Secretary of Health and Human Services to prescribe other requirements considered necessary in the interest of health and safety of beneficiaries. Section 1861 (o) of the Act provides:

> (o) The term "home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which—
>
> (1) Is primarily engaged in providing skilled nursing services and other therapeutic services;
>
> (2) Has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such

services by a physician or registered professional nurse;

(3) Maintains clinical records on all patients;

(4) In the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) Has in effect an overall plan and budget that meets the requirements of subsection (z); and

(6) Meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization; except that such term shall not include a private organization which is not a nonprofit organization exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954 (or a subdivision of such organization) unless it is licensed pursuant to State law and it meets such additional standards and requirements as may be prescribed in regulations; and except that for purposes of Part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases.

(b) The requirements included in the statute and the additional health and safety requirements prescribed by the Secretary are set forth in the conditions of participation for home health agencies.

§ 405.1202 Definitions.

As used in this subpart, the following definitions apply:

(a) *Administrator, home health agency.* A person who:

(1) Is a licensed physician; or

(2) Is a registered nurse; or

(3) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

(b) *Bylaws or equivalent.* A set of rules adopted by a home health agency for governing the agency's operation.

(c) *Branch office.* A location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

(d) *Clinical note.* A dated written notation by a member of the health team of a contact with a patient containing a description of signs and symptoms, treatment and/or drug given, the patient's reaction, and any changes in physical or emotional condition.

(e) *Nonprofit agency.* An agency exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954.

(f) *Occupational therapist.* A person who:

(1) Is a graduate of an occupational therapy curriculum accredited jointly by the Council on Medical Education of the American Medical Association and the American Occupational Therapy Association; or

(2) Is eligible for the National Registration Examination of the American Occupational Therapy Association; or

(3) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

(g) *Occupational therapy assistant.* A person who:

(1) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or

(2) Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

(h) *Parent home health agency.* The agency that develops and maintains administrative controls of subunits and/or branch offices.

(i) *Physical therapist.* A person who is licensed as a physical therapist by the State in which practicing, and

(1) Has graduated from a physical therapy curriculum approved by:

(i) The American Physical Therapy Association, or

(ii) The Council on Medical Education and Hospitals of the American Medical Association, or

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(2) Prior to January 1, 1966,

(i) Was admitted to membership by the American Physical Therapy Association, or

(ii) Was admitted to registration by the American Registry of Physical Therapists, or

(iii) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(3) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(4) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring physicians; or

(5) If trained outside the United States,

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy,

(iii) Has 1 year of experience under the supervision of an active member of the American Physical Therapy Association, and

(iv) Has successfully completed a qualifying examination as prescribed by the American Physical Therapy Association.

(j) *Physical therapist assistant.* A person who is licensed as a physical therapist assistant, if applicable, by the State in which practicing, and

(1) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(2) Has 2 years of appropriate experience as a physical therapist assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapist assistant after December 31, 1977.

(k) *Physician.* A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which such function or action is performed.

(l) *Practical (vocational) nurse.* A person who is licensed as a practical (vocational) nurse by the State in which practicing.

(m) *Primary home health agency.* The agency that is responsible for the service rendered to patients and for implementation of the plan of treatment.

(n) *Progress note.* A dated, written notation by a member of the health team summarizing facts about care and the patient's response during a given period of time.

(o) *Proprietary agency.* A private profit-making agency licensed by the State.

(p) *Public agency.* An agency operated by a State or local government.

(q) *Public health nurse.* A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study which includes content approved by the National League for Nursing for public health nursing preparation.

(r) *Registered nurse.* A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing.

(s) *Social work assistant.* A person who:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

(t) *Social worker.* A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

(u) *Speech pathologist or audiologist.* A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in the appropriate area (speech pathology or audiology) granted by the American Speech and Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(v) *Subdivision.* A component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for home health agencies. A subdivision which has subunits and/or branches is regarded as a parent agency.

(w) *Subunit.* A semi-autonomous organization, which serves patients in a geographic area different from that of the parent agency. The subunit by virtue of the distance between it and the parent agency is judged incapable of sharing administration, supervision, and services on a daily basis with the parent agency and must, therefore, independently meet the conditions of participation for home health agencies.

(x) *Summary report.* A compilation of the pertinent factors from the clinical notes and progress notes regarding a patient, which is submitted as a summary report to the patient's physician.

(y) *Supervision.* Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Unless otherwise provided in this subpart, the supervisor must be on the premises if the person does not meet qualifications for assistants specified in the definitions in this section.

§ 405.1220 Condition of participation: Compliance with Federal, State, and local laws.

The home health agency and its staff are in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of home health agencies, an agency not subject to licensure must be approved by the licensing authority as meeting the standards established for such licensure.

[47 FR 47391, Oct. 26, 1982 and 51 FR 23545, June 30, 1986]

§ 405.1221 Condition of participation: Organization, services, administration.

Organization, services provided, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable. Administrative and supervisory functions are not delegated to another agency or organization and all services not provided directly are monitored and controlled by the primary agency, including services provided through subunits of the parent agency. If an agency has subunits, appropriate administrative records are maintained for each subunit.

(a) *Standard: Services provided.* Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech, or occupational therapy; medical social services; or home health aide services) must be made available on a visiting basis, in a place of residence used as a patient's home. A home health agency must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

(b) *Standard: Governing body.* A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency. The governing body appoints a qualified administrator, arranges for professional advice (see § 405.1222), adopts and periodically reviews written bylaws or an acceptable equivalent, and oversees the management and fiscal affairs of the agency. The name and address of each officer, director, and owner are disclosed. If the agency is a corporation, all ownership interests of 10 percent or more (direct or indirect) are also disclosed.

(c) *Standard: Administrator.* The administrator, who may also be the supervising physician or registered nurse (see paragraph (d) of this section), organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

(d) *Standard: Supervising physician or registered nurse.* The skilled nursing and other therapeutic services provided are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person, or similarly qualified alternate, is available at all times during operating hours and participates in all activities relevant to the professional services provided, including the developing of qualifications and assignments of personnel.

(See Connecticut, Massachusetts, New Jersey, and Rhode Island Addenda in the Appendix.)

(e) *Standard: Personnel policies.* Personnel practices and patient care are supported by appropriate, written personnel policies. Personnel records include job descriptions, qualifications, licensure, performance evaluations, and health examinations, and are kept current.

(f) *Standard: Personnel under hourly or per visit contracts.* (1) If personnel under hourly or per visit contracts are utilized by the home health agency, there is a written contract between such personnel and the agency clearly designating:

(i) That patients are accepted for care only by the primary home health agency,

(ii) The services to be provided,

(iii) The necessity to conform to all applicable agency policies including personnel qualifications,

(iv) The responsibility for participating in developing plans of treatment,

(v) The manner in which services will be controlled, coordinated, and evaluated by the primary agency,

(vi) The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation, and

(vii) The procedures for determining charges and reimbursement.

(g) *Standard: Coordination of patient services.* All personnel providing services maintain liaison to assure that their efforts effectively complement one another and support the objectives outlined in the plan of treatment. The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordinated patient evaluation does occur. A written summary report for each patient is sent to the attending physician at least every 60 days.

(h) *Standard: Services under arrangements.* Services (see paragraph (a) of this section) provided under arrangements must be subject to a written contract conforming with the requirements specified in paragraph (f) of this section and with the requirements of section 1861(w) of the Act (42 U.S.C. 1395x(w)).

(i) *Standard: Institutional planning.* The home health agency, under the direction of the governing body, prepares an overall plan and budget which provides for an annual operating budget and a capital expenditure plan.

(1) *Annual operating budget.* There is an annual operating budget which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense).

(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period (including the year to which the operating budget described in paragraph (i)(1) of this section is applicable), which includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure in excess of $100,000 for items which would, under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $100,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions which are separated in time but are components of an overall plan or patient care objective are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of such financing is, in any part, the anticipated reimbursement from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Health Insurance for the Aged and Disabled) or title XIX (Grants to States for Medical Assistance Programs) of the Social Security Act, the plan states:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed pursuant to the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, to meet the need for adequate health care facilities in the area covered by the plan or plans so developed;

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval pursuant to section 1122 of the Social Security Act (42 U.S.C. 1320a-1) and implementing regulations; and

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it has been so presented.

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the home health agency by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the home health agency.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the home health agency.

[38 FR 18978, July 16, 1973, as amended at 40 FR 24325, June 5, 1975; 40 FR 56661, Dec. 4, 1975. Redesignated at 42 FR 52826, Sept.

30, 1977; 47 FR 47391, Oct. 26, 1982; 51 FR 23545, June 30, 1986]

§ 405.1222 Condition of participation: Group of professional personnel.

A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with appropriate representation from other professional disciplines, establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of treatment, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner (§ 405.1221(b)) nor an employee of the agency.

(a) *Standard: Advisory and evaluation function.* The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in its community information program. Its meetings are documented by dated minutes.

(See New Jersey Addendum in the Appendix.)

§ 405.1223 Condition of participation: Acceptance of patients, plan of treatment, medical supervision.

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of treatment established and periodically reviewed by a physician, and care continues under the supervision of a physician.

(a) *Standard: Plan of treatment.* The plan of treatment developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of treatment which cannot be completed until after an evaluation visit, the physician is consulted to approved additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of treatment.

(b) *Standard: Periodic review of plan of treatment.* The total plan of treatment is reviewed by the attending physician and home health agency personnel as often as the severity of the patient's condition requires, but at least once every 60 days. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of treatment.

(c) *Standard: Conformance with physician's orders.* Drugs and treatments are administered by agency staff only as ordered by the physician. The nurse or therapist immediately records and signs oral orders and obtains the physician's countersignature. Agency staff check all medicines a patient may be taking to identify possibly ineffective drug therapy or adverse reactions, significant side effects, drug allergies, and contraindicated medication, and promptly report any problems to the physician.

§ 405.1224 Condition of participation: Skilled nursing service.

The home health agency provides skilled nursing service by or under the supervision of a registered nurse and in accordance with the plan of treatment.

(See Connecticut, Massachusetts, and Rhode Island Addenda in the Appendix.)

(a) *Standard: Duties of the registered nurse.* The registered nurse makes the initial evaluation visit, regularly reevaluates the patient's nursing needs, initiates the plan of treatment and necessary revisions, provides those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, counsels the patient and family in meeting nursing and related needs, participates in inservice programs, and supervises and teaches other nursing personnel.

(b) *Standard: Duties of the licensed practical nurse.* The licensed practical nurse provides services in accordance with agency policies, prepares clinical and progress notes, assists the physician and/or registered nurse in performing specialized procedures, prepares equipment and materials for treatments observing aseptic technique as required, and assists the patient in learning appropriate self-care techniques.

§ 405.1225 Condition of participation: Therapy services.

Any therapy services offered by the home health agency directly or under arrangement are given by a qualified therapist or by a qualified therapist assistant under the supervision of a qualified therapist in accordance with the plan of treatment. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of treatment (revising as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in inservice programs.

(a) *Standard: Supervision of physical therapist assistant and occupational therapy assistant.* Services provided by a qualified physical therapist assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapist assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in inservice programs.

(b) *Standard: Supervision of speech therapy services.* Speech therapy services are provided only by or under supervision of a qualified speech pathologist or audiologist.

§ 405.1226 Condition of participation: Medical social services.

Medical social services, when provided, are given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of treatment. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of treatment, prepares clinical and progress notes, works with the family, utilizes appropriate community resources, participates in discharge planning and inservice programs, and acts as a consultant to other agency personnel.

§ 405.1227 Condition of participation: Home health aide services.

Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. Aides are carefully trained in methods of assisting patients to achieve maximum self-reliance, principles of nutrition and meal preparation, the aging process and emotional problems of illness, procedures for maintaining a clean, healthful, and pleasant environment, changes in patient's condition that should be reported, work of the agency and the health team, ethics, confidentiality, and recordkeeping. They are closely supervised to assure their competence in providing care.

(See Connecticut and Oregon Addenda in the Appendix.)

(a) *Standard: Assignment and duties of the home health aide.* The home health aide is assigned to a particular patient by a registered nurse. Written instructions for patient care are prepared by a registered nurse or therapist as appropriate. Duties include the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercise, household services essential to health care at home, assistance with medications that are ordinarily self-administered, reporting changes in the patient's conditions and needs, and completing appropriate records.

(b) *Standard: Supervision.* The registered nurse, or appropriate professional staff member, if other services are provided, makes a supervisory visit to the patient's residence at least every 2 weeks, either when the aide is present to observe and assist, or when the aide is absent, to assess relationships and determine whether goals are being met.

(See Massachusetts Addendum in the Appendix.)

§ 405.1228 Condition of participation: Clinical records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of treatment (see § 405.1223(a)), the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes (clinical notes are written the day service is rendered and incorporated no less often than weekly); copies of summary reports sent to the physician; and a discharge summary.

(a) *Standards: Retention of records.* Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the home health agency discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract accompanies the patient.

(b) *Standards: Protection of records.* Clinical record information is safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and conditions for release of information. Patient's written consent is required for release of information not authorized by law.

§ 405.1229 Condition of participation: Evaluation.

The home health agency has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), home health agency staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

(a) *Standard: Policy and administrative review.* As a part of the evaluation process the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation. The data to be considered may include but are not limited to: number of patients receiving each service offered, number of patient visits, reasons for discharge, breakdown by diagnosis, sources of referral, number of patients not accepted with reasons, and total staff days for each service offered.

(b) *Standard: Clinical record review.* At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to assure that established policies are followed in providing services (direct services as well as services under arrangement). There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of treatment and appropriateness of continuation of care.

§ 405.1230 Condition of participation: Qualifying to provide outpatient physical therapy or speech pathology services.

(a) Section 1861(p) of the Social Security Act provides in pertinent part as follows:

> (p) The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, a rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—* * *
>
> The term "outpatient physical therapy services" also includes speech pathology services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient, subject to the conditions prescribed in this subsection.

(b) As a provider of services, a home health agency may qualify to provide outpatient physical therapy or speech pathology services if such agency meets the statutory requirements of section 1861(o) of the Act and complies with other health and safety requirements prescribed by the Secretary for home health agencies, and, additionally, is in compliance with applicable health and safety requirements pertaining to rendition of outpatient physical therapy or speech pathology services. The applicable health and safety requirements pertaining to outpatient physical therapy or speech pathology services are included in the conditions of participation in Subpart Q of this part. (See §§ 405.1717, 405.1718, 405.1719, 405.1721, 405.1723, and 405.1725.)

[41 FR 20871, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

APPENDIX—ADDENDA FOR SEVERAL STATES INCORPORATING CONDITIONS OF PARTICIPATION HIGHER THAN THOSE IMPOSED BY THE HEALTH INSURANCE FOR THE AGED PROGRAM

ADDENDA TO § 405.1221(d)

Pursuant to the provisions of section 1863 of title XVIII of the Act, there are approved the following higher conditions of participation relating to agency supervision applicable in those States identified below:

CONNECTICUT

Agency supervision—condition. The home health agency designates a physician or registered professional nurse qualified as a public health nurse director or nursing supervisor to supervise the agency's performance in providing home health services in accordance with the orders of the physician responsible for the care of the patient and under a plan of treatment established by the physician. The following qualifications apply to the supervisor and director:

(a) *Supervisor—*(1) *Towns having a population of more than 30,000.* The minimum qualifications for a nursing supervisor are a baccalaureate degree from a university program in nursing approved by the National League for Nursing for public health nursing preparation, and a minimum of 2 years of experience in a public health nursing program under qualified nursing supervision which included supervisory responsibilities.

(2) *Towns having a population of 30,000 or less.* Any nursing supervisor shall be at least:

(i) A registered nurse, licensed to practice in Connecticut, with 5 years of experience as a nurse in charge of a visiting nurse agency or other home health agency; or

(ii) A registered nurse, licensed to practice in Connecticut, with a baccalaureate degree in nursing and 2 years of experience in a visiting nurse agency or other home health agency.

(b) *Director.* When a unit through which home health services are provided reaches a total nursing staff of 9 to 12, depending upon the number of towns involved and area served, a qualified public health nursing director shall be employed in addition to the nursing supervisor. The qualifications for the director are:

(1) *Preferred.* A master's degree with a major in public health nursing administration or supervision from a university program approved by the National League for Nursing, or a master's degree in public health from a university program approved by the American Public Health Association, and at least 5 years of experience in public health nursing, including 2 years under qualified supervision and 3 years as a supervisor.

(2) *Acceptable.* A baccalaureate degree from a university program in nursing approved by the National League for Nursing for public health nursing preparation, supplemented by approved courses in public health nursing supervision and administration, and at least 5 years of experience in public health nursing, including 2 years

under qualified supervision and 3 years as a supervisor.

MASSACHUSETTS

Agency supervision—condition. The home health agency designates a physician or registered professional nurse qualified as a public health nursing director and/or supervisor to direct the agency's services. In the event that a physician is the administrator of the home health agency, the nursing service shall be under the direction of a registered professional nurse qualified as a public health nursing director and/or supervisor. All home health services shall be provided in accordance with the orders of a physician responsible for the care of the patient and under a plan of treatment established by such physician.

(a) *Public Health Nursing Director—qualifications.* The public health nursing director is currently licensed to practice professional nursing by the State and meets the following requirements:

A master's degree with a major in public health nursing administration or supervision from a program approved by the National League for Nursing or a master's degree in public health from a program approved by the American Public Health Association, and at least 5 years of progressively responsible experience in public health nursing or community health nursing, some of which should be in supervision, teaching, and/or consultation.

(b) *Public Health Nursing Supervisor—qualifications.* The public health nursing supervisor meets the following minimum requirements:

A master's degree in nursing from a program approved by the National League for Nursing and 1 year of experience in a family-centered public health nursing program which included supervisory responsibilities, or a baccalaureate degree from a program approved by the National League for Nursing for public health nursing preparation and 2 years of the above-described experience.

NEW JERSEY

Agency supervision—condition. The home health agency designates a physician or registered professional nurse qualified as a public health nurse director or supervisor to supervise the agency's performance in providing home health services in accordance with orders of the physician responsible for the care of the patient and under a plan of treatment established by such physician. In the event that a physician is designated to supervise the agency's services, the nursing service shall be under the direction of a registered professional nurse qualified as a public health nurse director or supervisor. The following are the requirements for qualifying as a public health nurse director or supervisor:

(a) *Director.* A public health nurse director has completed.

(1) A master's degree program accredited by the National League for Nursing with a nursing major in supervision, teaching, consultation or administration and advanced study in a clinical specialty; or a master's program in public health in an institution accredited by the American Public Health Association; and

(2) Five years of experience in public health nursing, 1 year of which shall have been in a supervisory experience.

(b) *Supervisor.* A public health nurse supervisor has completed:

(1) A baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postbaccalaureate study which includes content approved by the National League for Nursing for public health nursing preparation; and

(2) Three years of experience in public health nursing under qualified nursing supervision.

RHODE ISLAND

Agency supervision—condition. The home health agency designates a physician or registered professional nurse qualified as a public health nurse director to direct the agency's services. In the event that a physician is the administrator of the home health agency, the nursing service shall be under the direction of a registered professional nurse qualified as a public health nurse director. All home health services shall be provided in accordance with the orders of the physician responsible for the care of the patient and under a plan of treatment established by such physician.

Public Health Nursing Director—Qualifications. The nursing director must meet one of the following requirements:

(a) *Preferred.* A master's degree with a major in public health nursing administration, supervision, or specialty from a university program approved by the National League for Nursing or a master's degree in public health from a university program approved by the American Public Health Association; and with a minimum of 5 years of experience with a generalized public health nursing service under qualified supervision and with supervisory experience in a public health nursing agency.

(b) *Acceptable.* A baccalaureate degree from a university program in nursing approved by the National League for Nursing for public health nursing preparation supplemented by approved courses in public health nursing supervision and administration, and at least 5 years of experience in public health nursing, including 2 years under qualified supervision and 3 years as a supervisor.

ADDENDUM TO § 405.1222

Pursuant to the provisions of section 1863 of title XVIII of the Act, there is approved the following higher condition bf participation relating to the Advisory Group of Professional Personnel in the State identified below:

NEW JERSEY

Advisory group of professional personnel—condition. Policies covering skilled nursing and other therapeutic services, and the professional health aspects of other policies, are established with the approval of and subject to regular review by a group of professional personnel which includes at least three licensed physicians and a registered professional nurse qualified as a public health nurse director or public health nurse supervisor.

Composition of group. (a) This group might be, for example: (1) An advisory committee to the agency's executive council or board of directors; (2) a subcommittee of such council or board: or (3) other similar arrangement.

(b) Some member or members of the professional group are persons not employed by the agency.

(c) The physician members of the Advisory Group serve as liaison with the County Medical Society and interpret agency medical policies to individual physicians.

(d) It is desirable for the group to include lay persons knowledgeable in health affairs and also to have a wide range of professional representatives such as social worker; nutritionist; speech, physical, and occupational therapists.

ADDENDA TO § 405.1224

Pursuant to the provisions of section 1863 of title XVIII of the Act, there are approved the following higher conditions of participation relating to skilled nursing services in those States identified below:

CONNECTICUT

Skilled nursing service—condition. Skilled nursing service is provided by or under the supervision of a public health nursing supervisor currently licensed by the State.

(a) *Professional nursing services—duties.* (The provisions of § 405.1224(a) are applicable.)

(b) *Public Health Nursing Supervisor—qualifications.* The public health nursing supervisor must have a baccalaureate degree from a university program in nursing approved by the National League for Nursing for public health nursing preparation, and a minimum of 2 years of experience in a public health nursing program under qualified nursing supervision which included supervisory responsibilities.

(c) *Registered Professional Nurse—qualifications.* (See § 405.1202.)

(d) *Public Health Nurse—qualifications.* (See § 405.1202.)

(e) *Practical nursing—duties.* (The provisions of § 405.1224(b) are applicable.)

(f) *Practical Nurse—qualifications.* (See § 405.1202.)

MASSACHUSETTS

Skilled nursing service—condition. Skilled nursing service is provided by or under the supervision of a qualified public health nursing director and/or supervisor. (See § 405.1221(d) regarding qualifications.)

RHODE ISLAND

Skilled nursing service—condition. Skilled nursing service is provided by or under the supervision of a qualified public health nursing supervisor currently licensed by the State.

(a) *Professional nursing services—duties.* (The provisions of § 405.1224(a) are applicable.)

(b) *Public Health Nursing Supervisor—qualifications.* A public health nursing supervisor is currently licensed to practice professional nursing by the State and has a baccalaureate degree from a university program in nursing approved by the National League for Nursing for public health nursing preparation and preferably with additional academic preparation in supervision and with experience in a public health nursing program under qualified nursing supervision for a minimum of 2 years.

(c) *Registered Professional Nurse—qualifications.* (See § 405.1202.)

(d) *Public Health Nurse—qualifications.* (See § 405.1202.)

(e) *Practical nursing—duties.* (The provisions of § 405.1224(b) are applicable.)

(f) *Practical nursing—qualifications.* (See § 405.1202.)

ADDENDA TO § 405.1227

Pursuant to the provisions of section 1863 of title XVIII of the Act, there are approved the following higher conditions of participation relating to home health aid in those States identified below:

CONNECTICUT

Training of Home Health Aides—condition. The home health agency determines that home health aides receive or have received a basic training program for home health aides approved by the Connecticut State Department of Health.

MASSACHUSETTS

Supervision of Home Health Aides—condition. The qualified nursing supervisor should provide direct supervision as necessary and is readily available at other times by telephone. The supervisor should be constantly evaluating the home health aide in terms of the aide's ability to carry out assigned duties, to relate well to the homebound patient, and to work effectively as a member of a team of health workers.

OREGON

Home Health Aide Services—condition. When a home health agency provides home health aide services, the home health aides are selected, trained, assigned and supervised.

Selection. Home health aides are currently registered with the State Board of Health as proof of qualification for employment as a home health aide.

Training. Home health aides complete an approved basic educational course for home health aides. All programs for home health aide training must be approved by the State Advisory Committee for Home Health Aide Programs.

[38 FR 18978, July 16, 1973, as amended at 41 FR 17893, Apr. 29, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

Subpart M—Conditions for Coverage of Services of Independent Laboratories

AUTHORITY: Secs. 1102, 1861(s)(10) and (11), 1864, 1871, 49 Stat. 647, as amended, 79 Stat. 322, 79 Stat. 325-326, 79 Stat. 331; 42 U.S.C. 1302, 1395x(s) (10) and (11), 1395aa, and 1395hh)).

SOURCE: 39 FR 33692, Sept. 19, 1974; 39 FR 36579, Oct. 11, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1310 Definitions.

For purposes of this Subpart M, the following definitions apply:

(a) *Independent laboratory.* An independent laboratory performing diagnostic tests means one which is independent both of the attending or consulting physician's office and of a hospital which meets at least the requirements specified in section 1861(e) of the Act to qualify for payment for emergency hospital services under section 1814(d) of the Act. A laboratory which:

(1) Is located in a hospital which meets at least the requirements specified in section 1861(e) of the Act to qualify for payment for emergency hospital services under section 1814(d) of the Act or, if outside the hospital, is operated under the supervision of the hospital or its organized medical staff, and (2) serves the hospital's patients, is not an independent laboratory. Services furnished by out-of-hospital laboratories under the direction of a physician, such as a pathologist, are considered to be subject to the conditions where the physician holds himself and the facilities of his office out to other physicians as being available for the performance of diagnostic tests. A laboratory maintained by a physician for performing diagnostic tests for his own patients is exempt from the conditions unless such laboratory accepts at least 100 specimens in any category during any calendar year on referral from other physicians. For purposes of this paragraph a category shall be one of the following:

(i) Microbiology and serology; (ii) clinical chemistry; (iii) immunohematology; (iv) hematology; (v) pathology; (vi) radiobioassay.

(b) *Clinical laboratory.* The term "clinical laboratory" means a facility for the microbiological, serological, chemical, hematological, radiobioassay, cytological, immunohematological, pathological or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or assessment of a medical condition.

(c) *Proficiency testing program.* A proficiency testing program is one which (1) is either operated or approved by the State agency, or by the Secretary, and (2) meets at a minimum the requirements for a proficiency testing program acceptable to the Secretary.

(d) *Subsequent to graduation.* The phrase "subsequent to graduation" means laboratory training and experience acquired after receipt of the degree specified. However, for purposes of § 405.1312 or § 405.1313, experience as a technologist in an approved clinical laboratory, which was gained prior to acquiring such degree, may be substituted on an equivalency basis of 1.5 years of such experience for every

1 year of postdegree training and experience; and experience as a general supervisor in an approved clinical laboratory, which was gained prior to acquiring such degree, may be substituted on a 1-for-1 basis.

(e) *Director at the doctoral level.* The term "director at the doctoral level" means a person having the qualifications described in § 405.1312(b) except for paragraphs (b)(5) (ii), (iii), and (iv).

(f) *Consultation.* A "consultation" is a communication between two or more physicians concerning the diagnosis or treatment in a given case. Consultation would, when indicated, include history taking, examination of the patient, and rendering to the attending physician an opinion concerning diagnosis and/or treatment.

(g) *Technician trainee.* The term "technician trainee" means a high school graduate or equivalent who is gaining the required 2 years of clinical laboratory on-the-job experience to qualify as a technician, and is participating in a structured training program approved by the State agency designed to provide the trainee with a broad range of laboratory procedures of progressive technical difficulty.

(h) *Personal and direct supervision.* The phrase "personal and direct supervision" means that a qualified general supervisor or supervisory cytotechnologist, where applicable, is present in the immediate bench area when laboratory procedures are being performed.

(i) *Approved clinical laboratory.* The term "approved clinical laboratory" means a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, medical research institution or military installation of the United States Government; or, a clinical laboratory approved under this subpart; or, a clinical laboratory licensed under The Clinical Laboratories Improvement Act of 1967; or, in a State which regulates clinical laboratory personnel, a clinical laboratory acceptable to that State.

(j) *Accredited.* The term "accredited" means having the approval conferred upon schools, institutions, or programs where appropriate by a nationally recognized accrediting agency or association as determined by the U.S. Commissioner of Education.

(k) *Substitution of education for experience.* The phrase "substitution of education for experience," applies only to §§ 405.1313(b)(5), 405.1315(b)(5), and 405.1315(e)(5) and means that a minimum of 30 semester hours of credit from an approved school of medical technology, or toward a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject is considered equivalent to 2 years of experience. Additional education is equated at the rate of 15 semester hours of credit for 1 year of experience.

(l) *Radiobioassay.* The term "radiobioassay" means (1) an examination to identify radionuclides or determine and quantitate body levels of radionuclides which are taken in by chronic or acute absorption, ingestion, or inhalation; and (2) following the administration of a radioactive material to a patient, the subsequent analysis of a body fluid, or excreta in order to evaluate body function.

(m) *Histocompatibility testing.* Laboratory test procedures which determine compatibility between a potential donor organ and a potential organ transplant recipient.

[39 FR 33692, Sept. 19, 1974, as amended at 40 FR 3765, Jan. 24, 1975; 41 FR 22510, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.1311 Condition—compliance with State and local laws.

The laboratory shall conform with all applicable State and local laws.

(a) *Standard; licensure.* Any laboratory located in any State in which State or applicable local law provides for the licensing of laboratories is (1) licensed pursuant to such law, or (2) approved, by the agency of the State or locality responsible for licensing laboratories, as meeting the standards established for such licensing.

(b) *Standard; licensed staff.* The director and the staff of the laboratory are licensed or registered in accordance with applicable laws.

(c) *Standard; fire and safety.* The laboratory is in conformity with laws relating to fire and safety, and to other relevant matters.

§ 405.1312 Condition—clinical laboratories; laboratory director.

The clinical laboratory is under the direction of a qualified person.

(a) *Standard; administration.* The laboratory has a director who administers the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests. The factors explaining the standard are as follows:

(1) The director serves the laboratory full time, or on a regular part-time basis. If on a regular part-time basis, he (i) does not individually serve as director of more than three laboratories (hospital or independent), or (ii) if he does individually serve as director of more than three laboratories, provides for an associate in each additional laboratory, qualified under the standard in paragraph (b) of this section, to serve as assistant director in each laboratory. Such assistant director does not serve more than three laboratories.

(2) Commensurate with the laboratory workload, the director spends an adequate amount of time in the laboratory to direct and supervise the technical performance of the staff and is readily available for personal or telephone consultation.

(3) The director is responsible for the proper performance of all tests made in the laboratory.

(4) The director is responsible for the employment of qualified laboratory personnel and their inservice training.

(5) If the director is to be continuously absent for more than 1 month, arrangements are made for a qualified substitute director.

(b) *Standard; laboratory director—qualification.* The laboratory director meets one of the following requirements:

(1) Is a physician certified in anatomical and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for such certification (board eligible);

(2) Is a physician who (i) is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties, or (ii) is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties, or (iii) is certified by the American Society of Cytology to practice cytopathology or possesses qualifications which are equivalent to those required for such certification (also see the last sentence of § 405.1314(b)(9)), or (iv) subsequent to graduation has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in an approved clinical laboratory;

(3) For the specialty of oral pathology only, is a dentist who is certified by the American Board of Oral Pathology or possesses qualifications which are equivalent to those required for certification (board eligible);

(4) Holds an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (i) is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to the Secretary in one of the laboratory specialties, or (ii) subsequent to graduation has had 4 or more years of full-time general clinical laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in an approved clinical laboratory; or

(5) With respect to individuals first qualifying prior to July 1, 1971, was responsible for the direction of a clinical laboratory for 12 months between July 1, 1961, and January 1, 1968, and in addition, met one of the following requirements:

(i) Was a physician and subsequent to graduation has had at least 4 years of pertinent full-time clinical laboratory experience;

(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation has had at least 4 years of pertinent full-time clinical laboratory experience;

(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation has had at least 6 years of pertinent full-time clinical laboratory experience; or

(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970.

NOTE: The January 1, 1968, date for meeting the 12 months laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time clinical laboratory experience obtained prior to January 1, 1968 required by State law for a clinical laboratory director license. An exception to the July 1, 1971, qualifying date in paragraph (b)(5) of this section will be made provided that the individual requests qualification approval no later than 1 year following the effective date of these regulations and such individual has been employed in an approved clinical laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

§ 405.1313 Condition—clinical laboratory; supervision.

The clinical laboratory is supervised by qualified personnel.

(a) *Standard; supervision.* The laboratory has one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, are held responsible for the proper performance of all laboratory procedures. A laboratory director who qualifies under § 405.1312(b) (1), (2), (4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor. The factors explaining the standard are as follows:

(1) *Required supervisors.* There are two categories of required supervisors. A general supervisor—one who meets the requirements of paragraph (b) of this section—is on the laboratory premises during all hours in which tests are being performed. With respect to the specialty of diagnostic cytology, cytotechnologists do not examine slide preparations unless a supervisor who qualifies pursuant to the provisions of § 405.1313(b)(4) or § 405.1314(b)(9) is on the premises at all times. A technical supervisor—one who meets the pertinent requirements of § 405.1314(b)—spends an adequate amount of time in the laboratory to supervise the technical performance of the staff in the specialty and is readily available for personal or telephone consultation. A general supervisor may also be a technical supervisor in those specialties in which the requirements of § 405.1314(b) are met.

(2) *Supervision of emergency procedures.* When emergencies arise outside regularly scheduled hours of duty, an individual who qualifies as a general supervisor is not required to be on the premises provided that the technologist performing tests is qualified to perform such tests, the supervisor who is responsible for the results of the work reviews them during the next duty period, and a record is maintained to reflect the actual review.

(b) *Standard; general supervisor—qualification.* The laboratory supervisor meets one of the following requirements:

(1)(i) Is a physician, or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and (ii) subsequent to graduation has had at least 2 years of experience in one of the laboratory specialities in an approved clinical laboratory;

(2)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and (ii) subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in an approved clinical laboratory;

(3)(i) Is qualified as a clinical laboratory technologist pursuant to the provisions of § 405.1315(b) (1), (2), (3), (4), or (6) and (ii) subsequent to the date of qualifying as a clinical laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in an approved clinical laboratory;

(4) With respect to the specialty of diagnostic cytology, qualifies as a supervisory cytotechnologist because he: (i) is qualified as a cytotechnologist pursuant to the provisions of § 405.1315(c) and (ii) has had 4 years of full-time experience as a cytotechnologist in a laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding 10 years; or

(5) With respect to individuals first qualifying prior to July 1, 1971, has had at least 15 years of pertinent full-time clinical laboratory experience prior to January 1, 1968; this required experience may be met by the substitution of education for experience.

§ 405.1314 Condition—clinical laboratory; tests performed.

The requirements of this section apply only to those tests and procedures performed for individuals enrolled under the supplementary medical insurance benefits program (see Subpart B of this Part 405). The clinical laboratory performs only those laboratory tests and procedures that are within the specialties or subspecialties in which the laboratory director or supervisors are qualified.

(a) *Standard: Proficiency testing.* All clinical laboratories must successfully participate in a proficiency testing program as defined in § 405.1310(c) covering all clinical laboratory and anatomical pathology specialties and subspecialties as made available in which the laboratory is approved to perform tests. Laboratories shall:

(1) Receive and examine and/or analyze specimens delivered by mail or messenger at such times as designated by the proficiency testing service; and

(2) Maintain records of all proficiency testing results in programs in which it is a participant and make such records, including results and interpretations routinely available to the State agency. An exception to the requirements of this paragraph may be made provided the State agency determines that an appropriate proficiency testing program is not readily available. Such exception, however, shall not be effective beyond the last day of the twelfth month following the effective date of these regulations, or the date the laboratory first requests approval for its services, whichever date is the later, unless no test exists for a specialty or subspecialty, in which case such exception shall continue until the State agency or the Secretary determines that such test has been developed and is available.

(b) *Standard; procedures and tests-competency.* The laboratory performs only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director or supervisors are qualified. The factors explaining the standard are as follows:

(1) If the laboratory director or supervisor is a physician certified in both (i) anatomical and (ii) clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification (board eligible), the laboratory may perform anatomical and clinical laboratory procedures and tests in all specialties.

(2) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, virology, mycology, and parasitology, the director or a supervisor (i) holds an earned doctoral or master's degree in microbiology from an accredited institution or is a physician, and (ii) subsequent to graduation has had at least 4 years of experience in clinical microbiology.

(3) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of serology, the director or a supervisor (i) holds an earned doctoral or master's degree in biology, chemistry, immunology, or microbiology from

an accredited institution or is a physician and, (ii) subsequent to graduation has had at least 4 years experience in serology.

(4) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of hematology, including gross and microscopic examination of the blood, the director or a supervisor (i) holds a master's or a bachelor's degree in biology, immunology, microbiology, or chemistry, or medical technology from an accredited institution, and (ii) subsequent to graduation has had at least 4 years of experience in hematology.

(5) If the requirements of paragraph (b)(1) of this section are not met and (i) the laboratory performs tests in the specialty of immunohematology, the director or a supervisor is a physician with at least 2 years of experience in immunohematology subsequent to graduation; or (ii) within the specialty of immunohematology, the laboratory performs tests in the subspecialities of ABO grouping and Rh typing, antibody detection, identification, and titering only, the director or a supervisor holds a master's or bachelor's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution and subsequent to graduation has had at least 4 years of experience in immunohematology.

(6) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of clinical chemistry, the director or a supervisor (i) holds an earned doctoral or master's degree in chemistry from an accredited institution or is a physician, and (ii) subsequent to graduation has had at least 4 years of experience in clinical chemistry.

(7) If the requirements of paragraph (b)(1) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the director or a supervisor (i) holds an earned doctoral, master's, or bachelor's degree in chemistry, physics, biology, or medical technology from an accredited institution or is a physician, and (ii) subsequent to graduation has had at least 4 years of experience in radiobioassay.

(8) If the laboratory performs tests in the specialty of tissue pathology, the director or a supervisor (i) meets the requirements of paragraph (b)(1)(i) of this section, or (ii) within the specialty of tissue pathology performs tests limited to skin pathology if the director or a supervisor is certified in dermatopathology by the American Board of Dermatology and American Board of Pathology or possesses qualifications which are equivalent to those required for certification (board eligible).

(9) If the requirements of paragraph (b)(1)(i) of this section are not met and the laboratory performs tests in the specialty of diagnostic cytology, the director or a supervisor, (i) is a physician who is certified by the American Society of Cytology to practice cytopathology or possesses qualifications which are equivalent to those required for certification (under this provision the laboratory is qualified to perform such tests only on that anatomic site for which the director or supervisor is certified); or (ii) is an individual who, pursuant to a request to establish his qualifications filed prior to January 1, 1971, has demonstrated competency (A) through at least 7 years of accumulative experience in a position of diagnostic responsibility in the field of clinical cytology or through 5 years of full-time training in diagnostic clinical cytology with suitable endorsement by a physician who has been supervisor in such activity; (B) by the publishing of treatises, texts, or other publications on the subject of diagnostic cytology which are generally acknowledged and recognized by the medical profession as authoritative in the field; (C) by appointment to and service in pertinent teaching and research positions in recognized schools of medicine; (D) by acceptance into or award of membership and office in professional societies in this field; and (E) by receipt of other professional honors for excellence in the use of procedures in exfoliative cytology for the diagnosis of a pathological condition (under this provision the laboratory is qualified to perform such tests only on that anatomic site with respect to which such competency is so established). The Health Care Fi-

nancing Administration, after documentation of the individual's qualifications by the State agency, will, with appropriate professional advice from Public Health Service, make all determinations with respect to the requirements set forth in this paragraph (b)(9)(ii). An individual who qualifies under this paragraph (b)(9)(ii) is deemed also to meet the requirements of § 405.1312(b)(2)(iii).

(10) If the requirements of paragraph (b)(1)(i) of this section are not met and the laboratory performs tests in oral pathology, the director or supervisor is a dentist who is certified in oral pathology by the American Board of Oral Pathology or possesses qualifications which are equivalent to those required for certification (board eligible).

(11) An exception to the requirements in paragraphs (b)(2), (3), (4), (5)(ii), (6), and (7) of this section is made with respect to an individual who qualifies as a director under § 405.1312(b)(5)(iii). The laboratory such individual directs may perform tests in:

(i) *Microbiology*: If the director has a bachelor's degree in a biological science and subsequent to graduation has had at least 6 years of experience in microbiology;

(ii) *Hematology*: If the director has a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of clinical laboratory experience of which at least 4 years of experience are in hematology;

(iii) *Serology*: If the director has a bachelor's degree in biology, chemistry, immunology, or microbiology and subsequent to graduation has had at least 6 years of experience in serology;

(iv) *Radiobioassay*: If the director has a bachelor's degree in a chemical, physical, or biological science and subsequent to graduation has had at least 6 years of laboratory experience at least 1 year of which is in radiobioassay;

(v) *Blood grouping and Rh typing, antibody detection, identification, and titering*: If the director has a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of clinical laboratory experience of which at least 4 years of experience are in immunohematology;

(vi) *Clinical chemistry*: If the director has a bachelor's degree in a chemical science or its equivalent and subsequent to graduation has had at least 6 years of experience in clinical chemistry;

(vii) *Any of the above specialties*: If the director has a bachelor's degree in medical technology and subsequent to graduation has had at least the designated years of specialized experience.

(12) A laboratory whose director qualifies under § 405.1312(b)(5)(iv) may perform tests in the laboratory specialties in which such director achieved a satisfactory grade in the examination conducted or sponsored by the Public Health Service. Further, a director who achieved a satisfactory grade in chemistry and/or blood grouping and Rh typing is deemed to meet the requirements of paragraphs (b)(5)(ii) and/or (7) of this section.

(13) Notwithstanding paragraph (b)(1) of this section, if the laboratory performs tests in the specialty of histocompatibility testing, the director or supervisor:

(i) Holds an earned doctoral degree in a biological science or is a physician and

(ii) Subsequent to graduation has had 4 years of experience in immunology, 2 of which have been in histocompatibility testing.

[39 FR 33692, Sept. 19, 1974, as amended at 41 FR 22510, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.1315 Condition—clinical laboratory; technical personnel.

The clinical laboratory has a sufficient number of properly qualified technical personnel for the volume and diversity of tests performed.

(a) *Standard; technologist—duties*. The laboratory employs a sufficient number of clinical laboratory technologists and/or cytotechnologists to proficiently perform under general supervision the clinical laboratory tests which require the exercise of independent judgment. The factors explaining the standard are as follows:

(1) The clinical laboratory technologists perform tests requiring the exercise of independent judgment and responsibility with minimal supervision by the director or supervisors only in those specialties or subspecialties in which the laboratory technologists are qualified by education, training, and experience.

(2) Specialties in which the clinical laboratory technologist is not qualified by education, training, or experience are performed only under the direct supervision of the laboratory supervisor or qualified technologist.

(3) Clinical laboratory technologists are in sufficient number to adequately supervise the work of technicians and trainees.

(4) An individual qualified as a cytotechnologist solely under paragraph (c) of this section may supervise technicians and trainees only in the specialty of cytology.

(b) *Standard; technologists—qualifications.* Each clinical laboratory technologist possesses a current license as a clinical laboratory technologist issued by the State, if such licensing exists, and:

(1) Has earned a bachelor's degree in medical technology from an accredited college or university; or

(2) Has successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or

(3) Has earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience and/or training in the specialty or subspecialty in which the individual performs tests; or

(4) Has successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses:

(i) *For those whose training was completed prior to September 15, 1963.* At least 24 semester hours in chemistry and biology courses of which:

(A) At least 6 semester hours were in inorganic chemistry *and* at least 3 semester hours were in other chemistry courses, and

(B) At least 12 semester hours in biology courses pertinent to the medical sciences, *or*

(ii) *For those whose training was completed after September 14, 1963.* (A) 16 semester hours in chemistry courses which included at least 6 semester hours in inorganic chemistry and which are acceptable toward a major in chemistry; and

(B) 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(C) 3 semester hours of mathematics; and

(iii) Has experience and/or training covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or

(5) With respect to individuals first qualifying prior to July 1, 1971; the technologist:

(i) Was performing the duties of an clinical laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 10 years of pertinent clinical laboratory experience prior to January 1, 1968 (This required experience may be met by the substitution of education for experience).

(6) Achieves a satisfactory grade in a proficiency examination approved by the Secretary.

(c) *Standard; cytotechnologists—qualifications.* Each laboratory cytotechnologist possesses a current license as a cytotechnologist issued by the State, if such licensing exists, and:

(1) Has successfully completed 2 years in an accredited college or university with at least 12 semester hours in science, 8 hours of which are in biology, and (i) has had 12 months of training in a school of cytotechnology

accredited by an accrediting agency approved by the Secretary, or (ii) has received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by the Secretary and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal 6 months of training, or

(2) Prior to January 1, 1969, has: (i) Been graduated from high school, (ii) completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and (iii) completed 2 years of full-time supervised experience in cytotechnology; or

(3) Achieves a satisfactory grade in a proficiency examination approved by the Secretary.

(d) *Standard; technician—duties.* Clinical laboratory technicians are employed in sufficient number to meet the workload demands of the laboratory and they function only under direct supervision of a clinical laboratory technologist. The factors explaining the standard are as follows:

(1) Each technician performs only those clinical laboratory procedures which required a degree of skill commensurate with the education, training, and technical abilities and which involve limited exercise of independent judgment.

(2) No clinical laboratory technician performs procedures in the absence of a qualified clinical laboratory technologist, supervisor, or director.

(3) A technician trainee performs only repetitive procedures which require a minimal exercise of independent judgment and he may perform such procedures only under the personal and direct supervision of a qualified supervisor or technologist.

(e) *Standard; technician—qualifications.* Each clinical laboratory technician possesses a current license as a clinical laboratory technician issued by the State, if such licensing exists, and meets one of the following requirements:

(1) Has successfully completed 60 semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution or has an associate degree based on a course of study including those subjects from an accredited institution;

(2) Is a high school graduate or equivalent and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by the Secretary;

(3) Is a high school graduate or equivalent and has 2 years of pertinent full-time laboratory experience as a technician trainee in an approved clinical laboratory;

(4) Is a high school graduate or equivalent and has successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

(5) With respect to a technician not meeting the training and experience requirements defined in paragraph (d) (1), (2), (3), or (4) of this section,

(i) Was performing the duties of a clinical laboratory technician any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 5 years of pertinent clinical laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience.)

(6) Achieves a satisfactory grade in a proficiency examination approved by the Secretary. However, after December 31, 1977, initial certification as a technician must be in accordance with paragraph (e) (1), (2), (3), or (4) of this section.

(f) *Standard; personnel policies.* There are written personnel policies, practices, and procedures that adequately support sound laboratory practice. The factors explaining the standard are as follows:

(1) Current employee records are maintained and include a resume of each employee's training, experience, duties, and date or dates of employment.

(2) Files contain evidence of adequate health supervision of employees, such as results of preemployment

physical examinations, including chest X-rays, immunization records, and records of all illnesses and accidents occurring on duty.

(3) Work assignments are consistent with qualifications.

[39 FR 33692, Sept. 19, 1974, as amended at 40 FR 3766, Jan. 24, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 44 FR 2594, Jan. 12, 1979]

§ 405.1316 Condition—clinical laboratory; management.

The clinical laboratory maintains records and facilities which are adequate and appropriate for the services offered.

(a) *Standard; laboratory procedure manual.* A compilation is kept of all automated and manual methods for tests which are performed in or offered by the laboratory. Each procedure is reviewed and dated by the technical supervisor at least annually. For those tests which are normally performed on automated test equipment, provision is made and documented for performing such tests by alternate methods, or for storing the test specimens, in the event this equipment becomes inoperable.

(b) *Standard; laboratory management.* Space and facilities are adequate to properly perform the services which are performed in or offered by the laboratory. The factors explaining the standards are as follows:

(1) Workbench space is ample, well-lighted, and convenient to sink, water, gas, and suction and electrical outlets as necessary.

(2) Work areas are arranged so as to minimize problems in transportation and communication.

(3) The laboratory is properly ventilated.

(4) Volatile chemicals and inflammable solvents are properly stored in areas unlikely to ignite same or restricted from open flame or heat.

(5) Temperature and humidity are controlled within limits required for proper performance of tests and operatiion of instruments affected by these variations.

(6) Voltage levels at electrical sources to which automated equipment is connected are monitored and recorded.

(7) Adequate fire precautions and occupational safety and health laws are known, posted, and observed insuring that there is freedom from unnecessary physical, chemical, and biological hazards.

(c) *Standard; collection of specimens.* No persons other than a licensed physician, or one otherwise authorized by law, manipulates a patient for the collection of specimens except that qualified technical personnel of the laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction or upon the written request of a licensed physician.

(d) *Standard; sterilization.* Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another are not reused unless they are properly sterilized prior to each use and wrapped in a manner which will insure that they remain sterile until used. Appropriate sterilization and disinfection techniques are utilized, as required, for tests performed on potentially contaminated material and for the protection of laboratory personnel. Disposable syringes, needles, pipettes, Petri dishes, and other disposable items are appropriately discarded immediately after use. Each sterilizing cycle contains a device which indicates proper sterilization or an adequate recording thermometer is used and records kept of temperature readings. Proper operation of the autoclave is checked monthly with viable spores or appropriate indicators.

(e) *Standard; examination and reports.* The laboratory examines specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and reports only to those authorized by law to receive such results. The factors explaining the standard are as follows:

(1) If the patient is sent to the laboratory, a written request for the desired laboratory procedures is obtained from a person authorized by law to use findings of laboratory examination.

(2) If only a specimen is sent, it is accompanied by a written request.

(3) If the laboratory receives reference specimens from another laborato-

ry, it reports back to the laboratory submitting the specimens.

(f) *Standard; specimens—records.* The laboratory maintains a record indicating the daily accession of specimens, each of which is numbered or otherwise appropriately identified. The factor explaining the standard is as follows: Records contain the following information:

(1) The laboratory number or other identification of the specimen.

(2) The name and other identification of the person from which the specimen was taken.

(3) The name of the licensed physician or other authorized person or clinical laboratory which submitted the specimen.

(4) The date the specimen was collected by the physician or other authorized person.

(5) The date the specimen was received in the laboratory.

(6) The condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed, or turbid, etc.).

(7) The type of test performed.

(8) The date that test was performed.

(9) The results of the laboratory test or cross-reference to results and the date of reporting.

(10) The name and address of the laboratory to which forwarded if the procedure is not performed at this laboratory.

(g) *Standard; laboratory report and record.* The laboratory report is sent promptly to the licensed physician or other authorized person who requested the test and a suitable record of each test result is preserved by the laboratory for a period of at least 2 years after the date of submittal of the report or for a period of time required by State law for such records, whichever is longer. The factors explaining the standard are as follows:

(1) The laboratory director is responsible for the laboratory report.

(2) Duplicate copies or a suitable record of laboratory reports are filed in the laboratory in a manner which permits ready identification and accessibility.

(3) Tissue pathology reports utilize acceptable terminology of a recognized system of disease nomenclature.

(4) The results of laboratory tests or procedures or transcripts thereof are not sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.

(5) Pertinent "normal" ranges as determined by the laboratory performing the tests are available to the physician requesting such tests.

(6) A list of analytical methods employed by the laboratory and a basis for the listed "normal" range is maintained in the laboratory. The list shall be made available to any physician ordering an examination upon request.

(7) If the laboratory refers specimens to another laboratory, the laboratory receiving the specimens meets the applicable conditions under the health insurance program. Each physician ordering an examination is notified that the specimen was referred to another laboratory. Such notice must show the name and address or other identification of the laboratory to which the specimen is referred. If the physician so requests, the referring laboratory may authorized the testing laboratory to report directly to the physician or other authorized person who requested the test, in which event the testing laboratory must send a duplicate of the report to the referring laboratory.

§ 405.1317 Condition—quality control.

(a) *Standard; general.* Quality controls imposed and practiced by the laboratory must provide for and assure:

(1) Preventive maintenance, periodic inspection, and testing for proper operatiion of equipment and instruments as may be appropriate; validation of methods; evaluation of reagents and volumetric equipment; surveillance of results; and remedial action to be taken in response to detected defects.

(2) Adequacy of facilities, equipment, instruments, and methods for performance of the procedures or categories of procedures for which a certification is approved; proper lighting for accuracy and precision; convenient location of essential utilities; monitoring of temperature-controlled spaces and equipment, including water baths

incubators, sterilizers, and refrigerators, to assure proper performance; evaluation of analytical measuring devices, such as photometers and radioactivity counting equipment, with respect to all critical operating characteristics.

(3) Labeling of all reagents and solutions to indicate identity, and when significant, titer, strength, or concentration, recommended storage requirements, preparation or expiration date, and other pertinent information. Materials of substandard reactivity and deteriorated materials may not be used.

(4) The availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a category (e.g., clinical chemistry, hematology, and pathology), of current laboratory manuals or other complete written descriptions and instructions relating to (i) the analytical methods used by those personnel, properly designated and dated to reflect the most recent supervisory reviews, (ii) reagents, (iii) control and calibration procedures, and (iv) pertinent literature references. Textbooks may be used as supplements to such written descriptions but may not be used in lieu thereof.

(5) Written approval by the director or supervisor of all changes in laboratory procedures.

(6) Maintenance and availability to laboratory personnel and to the Secretary of records reflecting dates and, where appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation, and changes and dates of changes in laboratory procedures.

(7) Solicitation designed to provide for collection, preservation, and transportation of specimens sufficiently stable to provide accurate and precise results suitable for clinical interpretation.

(b) *Standard; quality control system—methodologies.* Provision is made for an acceptable quality control program covering all types of analysis performed by the laboratory for verification and assessment of accuracy, measurement of precision, and detection of error. The factors explaining the standard are as follows:

(1) *Microbiology.* Chemical and biological solutions, reagents, and antisera shall be tested and inspected each day of use for reactivity and deterioration.

(i) *Bacteriology and mycology.* Staining materials shall be tested for intended reactivity by concurrent application to smears of micro-organisms with predictable staining characteristics. Each batch of medium shall be tested before or concurrently with use with selected organisms to confirm required growth characteristics, selectivity, enrichment, and biochemical response.

(ii) *Parasitology.* A reference collection of slides, photographs, or gross specimens of identified parasites shall be available and used in the laboratory for appropriate comparison with diagnostic specimens. A calibrated ocular micrometer shall be used for determining the size of ova and parasites, if size is a critical factor.

(iii) *Virology.* Systems for the isolation of viruses and reagents for the identification of viruses shall be available to cover the entire range of viruses which are etiologically related to clinical diseases for which services are offered. Records shall be maintained which reflect the systems used and the reactions observed. In tests for the identification of viruses, controls shall be employed which will identify erroneous results. If serodiagnostic tests for virus diseases are performed, requirements for quality control as specified for serology shall apply.

(2) *Serology.* (i) Serologic tests on unknown specimens shall be run concurrently with a positive control serum of known titer or controls of graded reactivity plus a negative control in order to detect variations in reactivity levels. Controls for all test components (antigens, complement, erythrocyte indicator systems, etc.) shall be employed to insure reactivity and uniform dosage. Test results shall not be reported unless the predetermined reactivity pattern of the controls is obtained.

(ii) Each new lot of reagent shall be tested concurrently with one of known acceptable reactivity before the new reagent is placed in routine use.

(iii) Equipment, glassware, reagents, controls, and techniques for tests for syphilis shall conform to those recommended in the "Manual of Tests for Syphilis 1969," U.S. Public Health Service Publication No. 411, January 1969.

(iv) All facilities performing transfusion of blood and blood products or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).

(3) *Clinical chemistry.* (i) Each instrument or other device shall be recalibrated or rechecked at least once on each day of use. Records which document the routine precision of each method, automated or manual, and its recalibration schedule shall be maintained and be available to laboratory personnel and the Secretary. At least one standard and one reference sample (control) shall be included with each run of unknown specimens where such standards and reference samples are available. Control limits for standards and reference samples shall be recorded and displayed and shall include the course of action to be instituted when the results are outside the acceptable limits.

(ii) Screening or qualitative chemical urinalysis shall be checked daily by use of suitable reference samples.

(4) *Immunohematology.* (i) ABO and Rho(D) grouping, antibody detection and identification, and compatibility testing must be performed according to the requirements of 21 CFR Part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR 640 et seq.

(A) ABO grouping shall be performed by testing unknown red cells with anti-A and anti-B grouping serums. For confirmation of ABO grouping, the unknown serum shall be tested with known group A1 and B red cells.

(B) The Rh$_o$ (D) group shall be determined by testing unknown red cells with anti-D (anti-Rh$_o$) blood grouping serum. All Rh$_o$ negative donor and patient cells shall be tested for the Rh$_o$ variant (D^u).

(C) A control system of patient
cells suspended in the patient's ow
serum or in albumin shall be employe
when the test is performed in a hig
protein medium.

(ii) Blood and blood product colle
tion, and processing and distributio
shall conform to the requirements o
21 CFR Part 640, subparts A, B, C, D
and F, except that the testing labora
tory must be a Medicare approved fa
cility.

(iii) Dating periods for blood an
blood products must conform to 2
CFR 610.53.

(5) *Hematology.* Instruments an
other devices used in hematologic
examination of specimens shall be re
calibrated or retested or reinspecte
as may be appropriate, each day o
use. Each procedure for which stan
ards and controls are available shall b
rechecked each day of use with stan
ards or controls covering the enti
range of expected values. Tests su
as the one-stage prothrombin time te
shall be run in duplicate unless th
laboratory can demonstrate that lo
frequency of random error or hig
precision makes such testing unnece
sary. Reference materials, such as he
moglobin pools, and stabilized cel
shall be tested at least once each da
of use to insure accuracy of resul
Standard deviation, coefficient of va
ation, or other statistical estimates o
precision shall be determined b
random replicate testing of specime
The accuracy and precision of blo
cell counts and hematocrit and hem
globin measurements shall be tes
each day of use.

(6) *Exfoliative cytology; histopath
logy; oral pathology*—(i) *Exfoliative c
tology.* The laboratory director or s
pervisor qualified in cytology or cy
technologist shall rescreen for prop
staining and correct interpretation a
least a 10-percent random sample o
gynecological smears which have be
interpreted to be in one of the ben
categories by personnel not posse
director or supervisor qualificatio
All gynecological smears interpre
to be in the "suspicious" or pos
categories by screeners shall be co
firmed by the laboratory director o
qualified supervisor and the rep
shall be signed by a physician qu

fied in pathology or cytology. All nongynecological cytological preparations, positive and negative, shall be reviewed by a director or supervisor qualified in cytology. Nonmanual methods shall provide quality control similar to that provided in other nonmanual laboratory procedures. All smears shall be retained for not less than 2 years from date of examination.

(ii) *Histopathology and oral pathology.* All special stains shall be controlled for intended reactivity by use of positive slides. Stained slides shall be retained for not less than 2 years from date of examination and blocks shall be retained for not less than 1 year from such date. Remnants of tissue specimens shall be retained in a fixative solution until those portions submitted for microscopy have been examined and a diagnosis made by a pathologist.

(7) *Radiobioassay.* The counting equipment shall be checked for stability at least once on each day of use, with radioactive standards or reference sources. Reference samples with known activity and within expected levels of normal samples shall be processed in replicate quarterly. For each method, records which document the routine precision and the recalibration schedule shall be maintained and be available to the staff and to the Secretary.

(8) *Histocompatibility testing.* In addition to the standards for quality control in immunohematology, paragraph (b)(4) of this section, and serology, paragraphs (b)(2)(i) and (b)(2)(ii) of this section, which are applicable to the histocompatibility testing laboratory, the histocompatibility testing laboratory utilizes the following control systems and validation methods for the performance of tests in the following:

(i) For renal allotransplantation: (A) Crossmatching of potential recipients and donors before transplantation is performed with one or more techniques using the most reactive and most recent sera;

(B) HL-A serologic typing of both donor and recipient which include at least those antigens detectable with serum capable of defining the same antigens as those definable by the National Institutes of Health serum tray(s); and,

(C) Characterization for antibody against histocompatibility antigens in serum from potential recipients of organ or tissue grafts.

(ii) For transfusions and bone marrow transplants the tests in paragraphs (b)(8)(i)(A) and (8)(i)(B) of this section are required.

(iii) For disease association studies, paragraph (b)(8)(i)(B) of this section applies.

(iv) Mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens are performed in accordance with prescribed methods.

(v) Procedures are established regarding freezing of lymphocytes and to provide for a comprehensive panel of fresh and/or frozen lymphocytes.

(vi) The reactivity of cell panels used for antibody detection is tested at least twice a month with appropriate known antisera.

(vii) The laboratory must also: (A) At least once each month have each individual performing tests be given a previously tested specimen as an unknown to verify their ability to reproduce test results and the results of such testing shall be recorded and,

(B) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

(9) [Reserved]

(10) Hepatitis testing requirements of 21 CFR 610.40 must be met for all facilities performing transfusion of blood or blood products or serving as referral laboratories for these facilities. Laboratories may offer the test within the specialty of clinical chemistry or within the specialty of serology.

(Secs. 1102, 1861(e)(9), 1861(s)(11) and 1871 of the Social Security Act; 42 U.S.C. 1302, 1395x(e)(9), 1395x(s)(11), and 1395hh)

[39 FR 33692, Sept. 19, 1976, as amended at 41 FR 22510, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 46 FR 41060, Aug. 14, 1981]

Subpart N—Conditions for Coverage of Portable X-ray Services

AUTHORITY: Secs. 1102, 1861(s) (3), (11) and (12), 1864, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(s) (3), (11), and (12), 1395aa and 1395hh).

SOURCE: 34 FR 388, Jan. 10, 1969, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1411 Conditions for coverage—compliance with Federal, State, and local laws and regulations.

The supplier of portable X-ray services is in conformity with all applicable Federal, State, and local laws and regulations.

(a) *Standard—licensure or registration of supplier.* In any State in which State or applicable local law provides for the licensure or registration of suppliers of X-ray services, the supplier is (1) licensed or registered pursuant to such law, or (2) approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

(b) *Standard—licensure or registration of personnel.* All personnel engaged in operating portable X-ray equipment are currently licensed or registered in accordance with all applicable State and local laws.

(c) *Standard—licensure or registration of equipment.* All portable X-ray equipment used in providing portable X-ray services is licensed or registered in accordance with all applicable State and local laws.

(d) *Standard—conformity with other Federal, State, and local laws and regulations.* The supplier of portable X-ray services agrees to render such services in conformity with Federal, State, and local laws relating to safety standards.

§ 405.1412 Condition for coverage—supervision by a qualified physician.

Portable X-ray services are provided under the supervision of a qualified physician.

(a) *Standard—physician supervision.* The performance of the roentgenologic procedures is subject to the supervision of a physician who meets the requirements of paragraph (b) of this section and one of the following requirements is met:

(1) The supervising physician owns the equipment and it is operated only by his employees, or

(2) The supervising physician certifies annually that he periodically checks the procedural manuals and observes the operators' performance, that he has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements and that safe operating procedures are used.

(b) *Standard—qualifications of the physician supervisor.* Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of X-rays for diagnostic purposes, i.e., he (1) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or possesses qualifications which are equivalent to those required for such certification, or (2) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes, or (3) specializes in radiology and is recognized by the medical community as a specialist in radiology.

§ 405.1413 Conditions for coverage—qualifications, orientation and health of technical personnel.

Portable X-ray services are provided by qualified technologists.

(a) *Standard—qualifications of technologists.* All operators of the portable X-ray equipment meet the requirements of paragraph (a) (1), (2), or (3) of this section:

(1) Successful completion of a program of formal training in X-ray technology of not less than 24 months' duration in a school approved by the Council on Education of the American Medical Association or by the American Osteopathic Association, or have earned a bachelor's or associate degree in radiologic technology from an accredited college or university.

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(2) For those whose training was completed prior to July 1, 1966, but on or after July 1, 1960: Successful completion of 24 full months of training and/or experience under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.

(3) For those whose training was completed prior to July 1, 1960: Successful completion of 24 full months of training and/or experience of which at least 12 full months were under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.

(b) *Standard—personnel orientation.* The supplier of portable X-ray services has an orientation program for personnel, based on a procedural manual which is: Available to all members of the staff, incorporates relevant portions of professionally recognized documents, and includes instruction in all of the following:

(1) Precautions to be followed to protect the patient from unnecessary exposure to radiation;

(2) Precautions to be followed to protect an individual supporting the patient during X-ray procedures from unnecessary exposure to radiation;

(3) Precautions to be followed to protect other individuals in the surrounding environment from exposure to radiation;

(4) Precautions to be followed to protect the operator of portable X-ray equipment from unnecessary exposure to radiation;

(5) Considerations in determining the area which will receive the primary beam;

(6) Determination of the time interval at which to check personnel radiation monitors;

(7) Use of the personnel radiation monitor in providing an additional check on safety of equipment;

(8) Proper use and maintenance of equipment;

(9) Proper maintenance of records;

(10) Technical problems which may arise and methods of solution;

(11) Protection against electrical hazards;

(12) Hazards of excessive exposure to radiation.

(c) *Standard: Employee records.* Records are maintained and include evidence that—

(1) Each employee is qualified for his or her position by means of training and experience; and

(2) Employees receive adequate health supervision.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988]

§ 405.1414 Condition for coverage—referral for service and preservation of records.

All portable X-ray services performed for Medicare beneficiaries are ordered by a doctor of medicine or doctor of osteopathy and records are properly preserved.

(a) *Standard—referral by a physician.* Portable X-ray examinations are performed only on the order of a doctor of medicine or doctor of osteopathy licensed to practice in the State. The supplier's records show that:

(1) The X-ray test was ordered by a licensed doctor of medicine or doctor of osteopathy, and

(2) Such physician's written, signed order specifies the reason an X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) *Standard—records of examinations performed.* The supplier makes for each patient a record of the date of the X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

(c) *Standard—preservation of records.* Such reports are maintained for a period of at least 2 years, or for the period of time required by State law for such records (as distinguished from requirements as to the radiograph itself), whichever is longer.

§ 405.1415 Condition for coverage—safety standards.

X-ray examinations are conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

(a) *Standard—tube housing and devices to restrict the useful beam.* The tube housing is of diagnostic type. Diaphragms, cones, or adjustable collimators capable of restricting the useful beam to the area of clinical interest are used and provide the same degree of protection as is required of the housing.

(b) *Standard—total filtration.* (1) The aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table except when contraindicated for a particular diagnostic procedure.

Operating kVp	Total filtration (inherent plus added)
Below 50 kVp	0.5 millimeters aluminum.
50-70 kVp	1.5 millimeters aluminum.
Above 70 kVp	2.5 millimeters aluminum.

(2) If the filter in the machine is not accessible for examination or the total filtration is unknown, it can be assumed that the requirements are met if the half-value layer is not less than that shown in the following table:

Operating kVp	Half-value layer
50 kVp	0.6 millimeters aluminum.
70 kVp	1.6 millimeters aluminum.
90 kVp	2.6 millimeters aluminum.
100 kVp	2.8 millimeters aluminum.
110 kVp	3.0 millimeters aluminum.
120 kVp	3.3 millimeters aluminum.

(c) *Standard—termination of exposure.* A device is provided to terminate the exposure after a preset time or exposure.

(d) *Standard—control panel.* The control panel provides a device (usually a milliammeter or a means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel includes appropriate indicators (labelled control settings and/or meters) which show the physical factors (such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

(e) *Standard—exposure control switch.* The exposure control switch is of the dead-man type and is so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

(f) *Standard—protection against electrical hazards.* Only shockproof equipment is used. All electrical equipment is grounded.

(g) *Standard—mechanical supporting or restraining devices.* Mechanical supporting or restraining devices are provided so that such devices can be used when a patient must be held in position for radiography.

(h) *Standard—protective gloves and aprons.* Protective gloves and aprons are provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.

(i) *Standard—restriction of the useful beam.* Diaphragms, cones, or adjustable collimators are used to restrict the useful beam to the area of clinical interest.

(j) *Standard—personnel monitoring.* A device which can be worn to monitor radiation exposure (e.g., a film badge) is provided to each individual who operates portable X-ray equipment. The device is evaluated for radiation exposure to the operator at least monthly and appropriate records are maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.

(k) *Standard—personnel and public protection.* No individual occupationally exposed to radiation is permitted to hold patients during exposures except during emergencies, nor is any other individual regularly used for this service. Care is taken to assure that pregnant women do not assist in portable X-ray examinations.

§ 405.1416 Condition for coverage—inspection of equipment.

Inspections of all X-ray equipment and shielding are made by qualified individuals at intervals not greater than every 24 months.

(a) *Standard—qualified inspectors.* Inspections are made at least every 24 months by a radiation health specialist who is on the staff of or approved by an appropriate State or local government agency.

(b) *Standard—records of inspection and scope of inspection.* The supplier maintains records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in § 405.1415.

Subparts C and P—[Reserved]

Subpart Q—Conditions of Participation: Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and/or Speech Pathology Services; and Conditions for Coverage: Outpatient Physical Therapy Services furnished by Physical Therapists in Independent Practice

AUTHORITY: Secs. 1102, 1861(p), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(p), 1395hh).

SOURCE: 41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

CONDITIONS OF PARTICIPATION: CLINICS, REHABILITATION AGENCIES, AND PUBLIC HEALTH AGENCIES AS PROVIDERS OF OUTPATIENT PHYSICAL THERAPY AND/OR SPEECH PATHOLOGY SERVICES

§ 405.1701 Conditions of participation—general.

(a) In order to participate in the program of health insurance for the aged and disabled as a provider of outpatient physical therapy and/or speech pathology services, a clinic, rehabilitation agency, or public health agency (other than a provider of services as defined in section 1861(u) of the Social Security Act, 42 U.S.C. 1395x(u)) must meet the requirements set forth in section 1861(p)(4) thereof, 42 U.S.C. 1395x(p)(4). This section of the law states a number of specific requirements which must be met by such participating providers and authorizes the Secretary of Health and Human Services to prescribe by regulation other requirements relating to the health and safety of beneficiaries as may be found necessary.

(b) Section 1861(p) provides in pertinent part as follows:

> (p) The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, a rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—
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> * * * * *
>
> excluding, however—
>
> (3) Any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital; and
>
> (4) Any such service—
>
> (A) If furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency—
>
> (i) Provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such program, in accordance with such requirements as the Secretary may specify,
>
> (ii) Has policies, established by a group of professional personnel, including one or

more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) Maintains clinical records on all patients,

(iv) If such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) Meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary, or

(B) If furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

* * * * *

The term "outpatient physical therapy services" also includes speech pathology services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient, subject to the conditions prescribed in this subsection.

(c) The specific requirements included in the statute and the additional health and safety requirements prescribed by the Secretary are set forth in the following Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and/or Speech Pathology Services.

§ 405.1702 Definitions relating to clinics, rehabilitation agencies, and public health agencies.

As used in §§ 405.1702–405.1726, the following definitions apply:

(a) *Administrator.* A person who has a bachelor's degree and:

(1) Has experience or specialized training in the administration of health institutions or agencies; or

(2) Is qualified and has experience in one of the professional health disciplines.

(b) *Clinic.* A facility established primarily for the provision of outpatient physicians' services. To meet this definition, an organization must meet the following test of physician participation:

(1) The medical services of the clinic are provided by a group of physicians (i.e., more than two) practicing medicine together; and

(2) A physician is present in the clinic at all times during hours of operation to perform medical services (rather than only administrative services).

(c) *Organization.* A clinic, rehabilitation agency, or public health agency.

(d) *Physical therapist.* A person who is licensed as a physical therapist by the State in which he or she is practicing if the State licenses physical therapists, and—

(1) Has graduated from a physical therapy curriculum approved by the American Physical Therapy Association, or by the Council on Medical Education and Hospitals of the American Medical Association, or jointly by the Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(2) Prior to January 1, 1966:

(i) Was admitted to membership by the American Physical Therapy Association; or

(ii) Was admitted to registration by the American Registry of Physical Therapists; or

(iii) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(3) Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State after December 31, 1977, or seeking qualification as a physical therapist after such date; or

(4) (i) Was licensed or registered prior to January 1, 1966, and

(ii) Prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(5) If trained outside the United States;

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy,

(iii) Has 1 year of experience under the supervision of an active member of the American Physical Therapy Association, and

(iv) Has successfully completed a qualifying examination as prescribed by the American Physical Therapy Association.

(e) *Physical therapist assistant.* A person who is licensed as a physical therapist assistant by the State in which he is practicing, if the State licenses such assistants, and has graduated from a 2-year college-level program approved by the American Physical Therapy Association.

(f) *Physician.* A person who is—

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs those functions or actions; or

(2) A doctor of podiatric medicine, but only with respect to the functions which he or she is legally authorized to perform by the State in which he or she performs them.

(g) *Psychologist.* A person who:

(1) Holds a doctoral degree in psychology from a training program approved by the American Psychological Association; or

(2) Has attained certification or licensing by the State, or non-statutory certification by the State psychological association.

(h) *Public health agency.* An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

(i) *Rehabilitation agency.* An agency which provides an integrated multidisciplinary program designed to upgrade the physical function of handicapped, disabled individuals by bringing together as a team specialized rehabilitation personnel. At a minimum, a rehabilitation agency must provide physical therapy or speech pathology services, and a rehabilitation program which in addition to physical therapy or speech pathology services, includes social or vocational adjustment services.

(j) *Social worker.* A person who is licensed by the State in which he is practicing if the State licenses social workers, is a graduate of a school of social work accredited or approved by the Council on Social Work Education, and has 1 year of social work experience in a health-care setting.

(k) *Speech pathologist.* A person who is licensed by the State in which he is practicing, if the State licenses speech pathologists, and

(1) Is eligible for a certificate of clinical competence in speech pathology granted by the American Speech and Hearing Association under its requirements in effect on January 17, 1974; or

(2) Meets the educational requirements for certification, and is in the process of accumulating the supervised clinical experience required for certification.

(l) *Supervision.* Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity within such person's sphere of competence, with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Unless otherwise stated in this Part 405, such qualified person must be on the premises if the person performing the function or activity does not meet assistant-level qualifications specified in this section.[1]

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[1] At 53 FR 12015, Apr. 12, 1988, § 405.1702 was amended by redesignating paragraphs

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(l) *Vocational specialist.* A person who has a baccalaureate degree and:

(1) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(2) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(3) A master's degree in vocational counseling.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apt. 12, 1988]

§ 405.1715 Condition of participation—compliance with Federal, State, and local laws.

The clinic, rehabilitation agency, or public health agency and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of organization.* In any State in which State or applicable local law provides for the licensing of clinics, rehabilitation agencies, or public health agencies, a clinic, rehabilitation agency, or public health agency is licensed pursuant to such law.

(b) *Standard: Licensure or registration of personnel.* Staff of the organization are licensed or registered in accordance with applicable laws.

§ 405.1716 Condition of participation—administrative management.

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body.* There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator.* The governing body appoints a qualified fulltime administrator and delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with established written policies. The administrator's responsibilities for procurement and direction of personnel are clearly defined. A competent individual is authorized to act in the temporary absence of the administrator.

(c) *Standard: Personnel policies.* Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure where applicable.

(d) *Standard: Patient care policies.* Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services which are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988]

§ 405.1717 Condition of participation—physician's direction and plan of care.

Patients in need of outpatient physical therapy or speech pathology services are accepted for treatment only on the order of a physician who indi-

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(f) through (k) as (g) through (l). The original paragraph (l) was not redesignated and will be corrected in a document published by the Health Care Financing Administration.

cates anticipated goals and is responsible for the general medical direction of such services as part of the total care of the patient. For each patient there is a written plan of care established and periodically reviewed by the physician. The organization has a physician available to furnish necessary medical care in case of emergency.

(a) *Standard: Medical findings and physician's orders.* The following is made available to the organization prior to or at the time of initiation of treatment:

(1) The patient's significant past history,

(2) Current medical findings,

(3) Diagnosis(es),

(4) Physician's orders,

(5) Rehabilitation goals, if determined,

(6) Contraindications, if any,

(7) The extent to which the patient is aware of the diagnosis(es) and prognosis, and

(8) Where appropriate, the summary of treatment rendered and results achieved during previous periods of physical therapy or speech pathology services or institutionalization.

(b) *Standard: Plan of Care.* For each patient there is a written plan of care established by the physician or, for speech pathology services, by the physician or by the speech pathologist who furnishes the services, or, for physical therapy services, by the physician or by the physical therapist who furnishes the services. The plan of care indicates anticipated goals and specifies the type, amount, frequency, and duration of physical therapy or speech pathology services. The plan of care and results of treatment are reviewed at least once every 30 days, by the attending or other physician, and the indicated action is taken.

(c) *Standard: General medical direction.* The organization requires that the health care of every patient is under the general medical direction of a physician. The patient in need of physical therapy and/or speech pathology services is seen by the physician at least once eevery 30 days. The organization is responsible for contacting the physician if the patient has not been seen by the physician within a 30-day period. There is evidence in the clinical record of the physician's services at appropriate intervals.

(d) *Standard: Notification of physician.* The attending physician, or where applicable, another responsible physician, is promptly notified of any changes in the patient's condition. If changes are required in the plan of care, such changes are approved by such physician and noted in the clinical record.

(e) *Standard: Emergency care.* The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in case of emergency. There are established procedures to be followed by personnel in an emergency, which cover immediate care of the patient, persons to be notified and reports to be prepared.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988]

§ 405.1718 Condition of participation—physical therapy services.

If physical therapy services are offered, the organization provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* (1) The organization will be considered to have an adequate outpatient physical therapy program if it can:

(i) Provide services utilizing therapeutic exercise and the modalities of heat, cold, water, and electricity;

(ii) Conduct patient evaluations; and

(iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer needed supervision to the physical therapist assistant when physical therapy services are provided on or off the organization's premises. Where a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled in such a manner as to ensure the physical therapist's presence when specific

skills are needed (e.g., the evaluation and reevaluation and to provide appropriate and needed supervision to the physical therapist assistant when providing services. When physical therapy services are provided off the premises of the organization by a qualified physical therapist assistant, such services are provided under the supervision of a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities accepted for service.

(c) *Standard: Personnel qualified to provide physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) *Standard: Supportive personnel.* If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, such personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

§ 405.1719 Condition of participation—speech pathology services.

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* The organization will be considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders accepted for service.

(c) *Standard: Personnel qualified to provide speech pathology services.* Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are rendered.

§ 405.1720 Condition of participation—rehabilitation program.

At a minimum, a rehabilitation agency provides physical therapy or speech pathology services, and a rehabilitation program which, in addition to physical therapy or speech pathology services, includes social or vocational adjustment services to all patients in need of such services by making provision for special, qualified staff to evaluate the social or vocational factors involved in a patient's rehabilitation, to counsel and advise on social or vocational problems arising from the patient's illness or injury, and to make appropriate referrals for required services.

(a) *Standard: Qualification of staff.* The agency's social or vocational adjustment services are rendered, as applicable, by qualified psychologists, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

(b) *Standard: Arrangements for social or vocational services.* If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide such adjustment services by means of a written contract with others which provides for retention by the agency of responsibility for, and control and supervision of, such services. The terms of the contract:

(1) Provide that the regimen of social or vocational adjustment services to be furnished is developed in consultation between appropriate professional staff members and the patient's attending physician;

(2) Specify the geographical areas in which the services are to be furnished;

(3) Provide that such services are furnished by personnel meeting the qualifications in § 405.1702;

(4) Provide that personnel under contract will participate as needed in conferences required to coordinate patient care;

(5) Provide for the preparation of treatment records and notes, and for the prompt incorporation of such into the clinical records of the agency;

(6) Specify the period of time the contract is to be in effect and the manner of termination or renewal.

§ 405.1721 Condition of participation—arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

When an organization provides outpatient physical therapy and/or speech pathology services under an arrangement with others, such services are to be furnished in accordance with the terms of a written contract, which provides for retention by the organization of professional and administrative responsibility for, and control and supervision of, such services.

(a) *Standard: Contract provisions.* The terms of the contract:

(1) Provide that physical therapy and/or speech pathology services are to be furnished in accordance with the plan of care established by the physician responsible for the patient's care and may not be altered in type, amount, frequency, or duration by the physical therapist or speech pathologist (except in the case of an adverse reaction to a specific treatment);

(2) Specify the geographical areas in which the services are to be furnished;

(3) Provide that personnel and services contracted for meet the same requirements as those which would be applicable if the personnel and services were furnished directly by the clinic, rehabilitation agency, or public health agency;

(4) Provide that as needed the physical therapist or speech pathologist (as appropriate) will participate in conferences required to coordinate the care of an individual patient;

(5) Provide for the preparation of treatment records, with progress notes and observations, and for the prompt incorporation of such into the clinical records of the clinic, rehabilitation agency, or public health agency;

(6) Specify the financial arrangements which provide that the contracting outside resource may not bill the patient or the health insurance program for covered services, since pursuant to section 1861(w) of the Act (42 U.S.C. 1395x(w)), covered services furnished under arrangements must be billed through the provider exclusively and receipt of payment by the provider for such services on behalf of an entitled individual discharges the liability of such individual or any other person to pay for such services;

(7) Specify the period of time the contract is to be in effect and the manner of termination or renewal;

(8) Except as provided in paragraph (a)(9) of this section, provide that the services shall be performed in the patient's home, on the premises of the clinic, rehabilitation agency, or public health agency making the arrangements, or on the premises of an institution which meets the requirements of section 1861(e)(1) or section 1861(j)(1) of the Act; and

(9) In the case of a public health agency (including a public health agency which is certified by the health insurance program as a home health agency), may provide that physical therapy and/or speech pathology services may also be performed on the premises of the supplier of such services but only under the following circumstances:

(i) The public health agency does not have the capacity to provide on its premises all of the:

(A) Modalities of treatment, tests, and measurements as specified in § 405.1718(a) (in the case of outpatient physical therapy services), or

(B) Diagnostic and treatment services as specified in § 405.1719(a) (in the case of outpatient speech pathology services);

(ii) The services provided on the premises of the supplier include those as defined in § 405.1718(a) or § 405.1719(a), as appropriate, which the public health agency cannot provide on its premises, and these services are not provided on an outpatient basis in another accessible participating provider of services;

(iii) Services are provided on the premises of the supplier only in those instances in which the patient's treatment requires the use of a modality or regimen which is not available on the premises of the public health agency;

(iv) The public health agency is responsible for advising the State agency of the name of each supplier with whom it contracts for the provision of services and makes the arrangements necessary in order for the State agency to survey the premises and organization of each supplier of services to determine compliance with applicable regulations; and

(v) A physician, qualified physical therapist, qualified speech pathologist, or supervising nurse employed by the public health agency reviews at least every 2 weeks all records of the patients of the public health agency who have been treated on the premises of the supplier.

§ 405.1722 Condition of participation—clinical records.

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services provided,

(2) Identification data and consent forms,

(3) Medical history,

(4) Report of physical examinations, if any,

(5) Observations and progress notes,

(6) Reports of treatments and clinical findings, and

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician's entries into the clinical record are signed by the appropriate physician.

(d) *Standard: Retention and preservation.* Clinical records are retained for a period of time not less than:

(1) That determined by the respective State statute, or the statute of limitations in the State, or

(2) In the absence of a State statute:

(i) Five years after the date of discharge, or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

§ 405.1723 Condition of participation—physical environment.

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

(a) *Standard: Safety of patients.* The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the organization considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the organization. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) *Standard: Maintenance of equipment, building, and grounds.* The organization establishes a written preventive-maintenance program to ensure:

(1) That equipment is operative, and is properly calibrated, and

(2) That the interior and exterior of the building are clean and orderly and maintained free of any defects which are a potential hazard to patients, personnel, and the public.

(c) *Standard: Other environmental considerations.* The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow utilization by nonambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

§ 405.1724 Condition of participation—infection control.

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection-control committee.* The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) *Standard: Aseptic and isolation techniques.* Written effective procedures in aseptic techniques are followed by all personnel. Procedures are reviewed and revised annually for effectiveness and improvement.

(c) *Standard: Housekeeping.* The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of such personnel. An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization and/or outside resource meets the requirements of the standard.

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization is maintained free from insects and rodents through operation of a pest-control program.

§ 405.1725 Condition of participation—disaster preparedness.

The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

(a) *Standard: Disaster plan.* The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

(1) Transfer of casualties and records;

(2) The location and use of alarm systems and signals;

(3) Methods of containing fire;

(4) Notification of appropriate persons; and

(5) Evacuation routes and procedures.

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988]

§ 405.1726 Condition of participation—program evaluation.

The organization has procedures which provide for a systematic evaluation of its total program to assure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to assure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of such statistical data as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

CONDITIONS FOR COVERAGE: OUTPATIENT PHYSICAL THERAPY SERVICES FURNISHED BY PHYSICAL THERAPISTS IN INDEPENDENT PRACTICE

§ 405.1730 Conditions for coverage—Services furnished by physical therapists in independent practice—General.

(a) In order to be covered under the program of health insurance for the aged and disabled as a supplier of outpatient physical therapy services, a physical therapist in independent practice must meet State licensure and requirements set forth in section 1861(p)(4) of the Act, 42 U.S.C. 1395x(p)(4), and other requirements established pursuant to this provision. This section of the law states specific requirements which must be met by such suppliers and authorizes the Secretary of Health and Human Services to prescribe by regulation other requirements relating to the health and safety of beneficiaries as may be found necessary.

(b) Section 1861(p) provides in pertinent part as follows:

> (p) The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or

> public health agency to an individual as an outpatient—
>
> * * * * *
>
> The term "outpatient physical therapy services" also includes physical therapy services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary * * *

(c) The requirements included in the statute and the additional health and safety requirements prescribed by the Secretary are set forth in the Conditions for Coverage for Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice (see §§ 405.1732 to 405.1737).

§ 405.1731 Definitions relating to physical therapists in independent practice.

As used in §§ 405.1731 through 405.1737, the following definitions apply:

(a) *Physical therapist.* A person who is licensed as a physical therapist by the State in which he is practicing if the State licenses physical therapists, and—

(1) Has graduated from a physical therapy curriculum approved by the American Physical Therapy Association, or by the Council on Medical Education and Hospitals of the American Medical Association, or jointly by the Council on Medical Education of the American Medical Association and the American Physical Therapy Association, or

(2) Prior to January 1, 1966:

(i) Was admitted to membership by the American Physical Therapy Association, or

(ii) Was admitted to registration by the American Registry of Physical Therapists, or

(iii) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(3) Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination approved by the Secretary except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State after December 31, 1977, or seeking qualification as a physical therapist after such date; or

(4) (i) Was licensed or registered prior to January 1, 1966, and

(ii) Prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(5) If trained outside the United States:

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy,

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy,

(iii) Has 1 year of experience under the supervision of an active member of the American Physical Therapy Association, and

(iv) Has successfully completed a qualifying examination as prescribed by the American Physical Therapy Association.

(b) *Physical therapist in independent practice:* A person who is licensed as a physical therapist by the State in which he is practicing, meets one of the qualification requirements in paragraph (a) of this section, and furnishes services under the circumstances described in § 405.232(e)(2)(ii).

(c) *Supervision:* The presence, at all times, of a qualified physical therapist when physical therapy services are rendered in the physical therapist's office or in the patient's place of residence.

(d) *Physician.* A person who is—

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs these functions or actions; or

(2) A doctor of podiatric medicine, but only with respect to the functions

which he or she is legally authorized to perform by the State in which he or she performs them.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988]

§ 405.1732 Condition for coverage—compliance with Federal, State, and local laws.

The physical therapist in independent practice and staff, if any, are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of facility.* In any State in which State or applicable local law provides for the licensing of the facility of a physical therapist, such facility is:

(1) Licensed pursuant to such law; or

(2) If not subject to licensure, is approved (by the agency of such State or locality responsible for licensing) as meeting the standards established for such licensing.

(b) *Standard: Licensure or registration of personnel.* The physical therapist in independent practice and staff, if any, are licensed or registered in accordance with applicable laws.

§ 405.1733 Condition for coverage—physician's direction and plan of care.

Patients in need of outpatient physical therapy services are accepted for treatment by the physical therapist in independent practice only on the order of a physician who indicates anticipated goals and is responsible for the general medical direction of such services as part of the total care of the patient. For each patient, there is a written plan of care established and periodically reviewed by the physician.

(a) *Standard: Medical findings and physician's orders.* The following is made available to the physical therapist, prior to or at the time of initiation of treatment:

(1) The patient's significant past history,

(2) Diagnosis(es),

(3) Physician's orders,

(4) Rehabilitation goals and potential for their achievement,

(5) Contraindications, if any,

(6) The extent to which the patient is aware of the diagnosis(es) and prognosis, and

(7) Where appropriate, the summary of treatment provided and results achieved during previous periods of physical therapy services or institutionalization.

(b) *Standard: Plan of care.* For each patient there is a written plan of care established by the physician or by the physical therapist who furnishes the services, which indicates anticipated goals and specifies the type, amount, frequency, and duration of physical therapy services. The plan of care and results of treatment are reviewed at least once every 30 days by the attending or other physician and the indicated action is taken.

(c) *Standard: General medical direction.* Patients are seen by a physician at least once every 30 days. General medical direction at appropriate intervals is evident from the clinical record.

(d) *Standard: Notification of physician.* The attending physician is promptly notified of any changes in the patient's condition. If changes are required in the plan of care, such changes are approved by such physician and noted in the clinical record.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988]

§ 405.1734 Condition for coverage—physical therapy services.

The physical therapist in independent practice provides an adequate program of physical therapy services and has the facilities and equipment necessary to carry out the services offered.

(a) *Standard: Adequate program.* The physical therapist will be considered to have an adequate physical therapy program when services can be provided, utilizing therapeutic exercise and the modalities of heat, cold, water, and electricity; patient evaluations are conducted; and tests and measurements of strength, balance, endurance, range of motion, and activities of daily living are administered.

(b) *Standard: Supervision of physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist.

§ 405.1735 Condition for coverage—coordination of services with other organizations, agencies, or individuals.

The physical therapy services provided by the physical therapist in independent practice are coordinated with the health and medical services provided to the patient by organizations, agencies, or individuals.

(a) *Standard: Exchange of clinical records and reports.* When a patient is receiving or has recently received health and medical services from providers, organizations, physicians, or others that are related to and that may involve the physical therapy program, the physical therapist shall, on a regular basis, exchange with such providers, organizations, physicians, or others in accordance with § 405.1736(a) documented information which has a bearing on the patient's health and welfare so as to ensure that services effectively complement one another.

§ 405.1736 Condition for coverage—clinical records.

The physical therapist in independent practice maintains clinical records on all patients in accordance with accepted professional standards and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* Clinical-record information is recognized as confidential and is safeguarded against loss, destruction, or unauthorized use. Written procedures govern use and removal of records and include conditions for release of information. A patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services provided,

(2) Identification data and consent forms,

(3) Medical history,

(4) Report of physical examination(s), if any,

(5) Observations and progress notes,

(6) Reports of treatments and clinical findings, and

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for a period of time not less than:

(1) That determined by the respective State statute or the statute of limitations in the State, or

(2) In the absence of a State statute: (i) 5 years after the date of discharge or, (ii) in the case of a minor, 3 years after the patient becomes of age under State law, or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical clinical information and retrieval of records for administrative action.

§ 405.1737 Condition for coverage—physical environment.

The physical environment of the office and/or facility of the physical therapist in independent practice affords a functional, sanitary, safe, and comfortable surrounding for patients, personnel, and the public.

(a) *Standard: Building construction.* The construction of the building housing the physical therapy office meets all applicable State and local building, fire, and safety codes.

(b) *Standard: Maintenance of the physical therapy office and equipment.* There is established a written preventive-maintenance program to ensure that equipment is operative and that the physical therapy office is clean and orderly. All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition, and is properly calibrated.

(c) *Standard: Other environmental considerations.* The building housing the physical therapy office is accessible to, and functional for, patients, personnel, and the public. Written effective procedures in aseptic techniques are followed by all personnel and such procedures are reviewed annually, and when necessary, revised.

(d) *Standard: Emergency procedures.* The physical therapist is aware of the possibility of the occurrence of fire and other non-medical emergencies and has documented:

(1) A means of providing for safe patient egress from the physical therapy office and the building housing the office, such means being demonstrated by fire exit signs, etc., and

(2) other such provisions necessary to ensure the safety of patients.

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1801 Introduction.

(a) *Definitions.* As used in this subpart: "Administrator" means the Administrator or Deputy Administrator of HCFA.

"Administrator's review" means that review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and § 405.1875.

"Board" means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 1395oo) and § 405.1845.

"Board hearing" means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 1395oo(a)), and § 405.1835.

"Date of filing" and "date of submission of materials" mean the day of the mailing (as evidenced by the postmark) or hand-delivery of materials, unless otherwise defined in this subpart.

"Date of receipt" means the date on the return receipt of "return receipt requested" mail, unless otherwise defined in this subpart.

"Intermediary determination" means the following:

(1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24(f) of this chapter, the term means a determination of the amount of total reimbursement due the provider, pursuant to § 405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (Part 412 of this chapter), the term means a determination of the total amount of payment due the hospital, pursuant to § 405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases "intermediary's final determination" and "final determination of the Secretary", as those phrases are used in section 1878(a) of the Act.

(4) For purposes of § 405.374 concerning claims collection activities, the term does not include an action by HCFA with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

"Intermediary hearing" means that hearing provided for in § 405.1809.

(b) *General rule*—(1) *Providers.* The principles of reimbursement for determining reasonable cost and prospective payment are contained in Parts 413 and 412, respectively, of this chapter. In order to be reimbursed for covered services furnished to Medicare beneficiaries, providers of services are obliged to file cost reports with their intermediaries as specified in § 413.24(f) of this chapter. Where the term "provider" appears in this subpart, it includes hospitals paid under the prospective payment system for purposes of applying the appeal procedures described in this subpart to those hospitals.

(2) *Other entities participating in Medicare Part A.* In addition to providers of services whose status as such is indicated in the Act, there are entities (such as health maintenance organizations) that do not meet the statutory test for providers of services, which may also participate in Medicare. These entities are required to file periodic cost reports and are reimbursed on the basis of information furnished in the reports. Although the entities do not qualify for Board review, the rules as set forth in this subpart with respect to intermediary hearings are applicable to the entities to the maximum extent possible, for cost-reporting periods ending on or after December 31, 1971, where the amount of program reimbursement in controversy is at least $1,000.

(c) *Effective dates.* (1) Except as provided in paragraphs (c)(2) and (c)(3) of this section or in § 405.1885(e), this subpart applies to all cost reporting periods ending on or after December 31, 1971, for which reimbursement may be made on a reasonable cost basis.

(2) Sections 405.1835 to 405.1877 apply only to cost reporting periods ending on or after June 30, 1973, for which reimbursement may be made on a reasonable cost basis.

(3) With respect to hospitals under the prospective payment system (see Part 412 of this chapter), the appeals procedures in §§ 405.1811 to 405.1877 that apply become applicable with the hospital's first cost reporting period beginning on or after October 1, 1983.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 39834, Sept. 1, 1983; 48 FR 45773, Oct. 7, 1983; 49 FR 322, Jan. 3, 1984; 49 FR 23013, June 1, 1984; 51 FR 34793, Sept. 30, 1986]

§ 405.1803 Intermediary determination and notice of amount of program reimbursement.

(a) *General requirement.* Upon receipt of a provider's cost report, or amended cost report where permitted or required, the intermediary must within a reasonable period of time (see § 405.1835(b)), furnish the provider and other parties as appropriate (see § 405.1805) a written notice reflecting the intermediary's determination of the total amount of reimbursement due the provider. The intermediary must include the following information in the notice, as appropriate:

(1) *Reasonable cost.* The notice must—

(i) Explain the intermediary's determination of total program reimbursement due the provider on the basis of reasonable cost for the reporting period covered by the cost report or amended cost report; and

(ii) Relate this determination to the provider's claimed total program reimbursement due the provider for this period.

(2) *Prospective payment.* With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (see Part 412 of this chapter), the intermediary must include in the notice its determination of the total amount of the payments due the hospital under that system for the cost reporting period covered by the notice. The notice must explain (with appropriate use of the applicable money amounts) any difference in the amount determined to be due, and the amounts received by the hospital during the cost reporting period covered by the notice.

(b) *Requirements for intermediary notices.* The intermediary must include in each notice appropriate references to law, regulations, HCFA Rulings, or program instructions to explain why the intermediary's determination of the amount of program reimbursement for the period differs from the amount the provider claimed. The notice must also inform the provider of its right to an intermediary or Board hearing (see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843) and that the provider must request the hearing within 180 days after the date of the notice.

(c) *Use of notice as basis for recovery of overpayments.* The intermediary's determination as contained in its notice constitutes the basis for making the retroactive adjustment (required by § 413.64(f) of this chapter) to any program payments made to the provider during the period to which the determination applies, including the suspending of further payments to the provider in order to recover, or to aid in the recovery of, any overpayment identified in the determination to have been made to the provider, notwithstanding any request for hearing on the determination the provider may make under § 405.1811 or § 405.1835. Any suspension will remain in effect as specified in § 405.373(a).

[48 FR 39834, Sept. 1, 1983, as amended at 49 FR 322, Jan 3, 1984; 51 FR 34793, Sept. 30, 1986]

§ 405.1804 Matters not subject to administrative and judicial review under prospective payment.

Neither administrative nor judicial review is available for controversies about the following matters:

(a) The determination of the requirement, or the proportional amount, of any budget neutrality adjustment in the prospective payment rates.

(b) The establishment of—

(1) Diagnosis related groups (DRGs);

(2) The methodology for the classification of inpatient discharges within the DRGs; or

(3) Appropriate weighting factors that reflect the relative hospital resources used with respect to discharge within each DRG.

[49 FR 322, Jan. 1, 1984]

§ 405.1805 Parties to intermediary determination.

The parties to the intermediary's determination are the provider and any other entity found by the intermediary to be a related organization of the provider under § 413.17 of this chapter.

[48 FR 39835, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§ 405.1807 Effect of intermediary determination.

The determination shall be final and binding on the party or parties to such determination unless:

(a) An intermediary hearing is requested in accordance with § 405.1811 and an intermediary hearing decision rendered in accordance with § 405.1831; or

(b) The intermediary determination is revised in accordance with § 405.1885; or

(c) A Board hearing is requested in accordance with § 405.1835 and a hearing decision rendered pursuant thereto.

§ 405.1809 Intermediary hearing procedures.

(a) *Hearings.* Each intermediary must establish and maintain written procedures for intermediary hearings, in accordance with the regulations in this subpart, for resolving issues that may arise between the intermediary and a provider concerning the amount of reasonable cost reimbursement, or prospective payment due the provider (except as provided in § 405.1804) under the Medicare program. The procedures must provide for a hearing on the intermediary determination contained in the notice of program reimbursement (§ 405.1803), if the provider files a timely request for a hearing.

(b) *Amount in controversy.* In order for an intermediary to grant a hearing, the following dates and amounts in controversy apply:

(1) For cost reporting periods ending prior to June 30, 1973, the amount of program reimbursement in controversy must be at least $1000.

(2) For cost reporting periods ending on or after June 30, 1973, the amount of program reimbursement in controversy must be at least $1000 but less than $10,000.

[48 FR 39835, Sept. 1, 1983, as amended at 49 FR 323, Jan. 1, 1984]

§ 405.1811 Right to intermediary hearing; time, place, form, and content of request for intermediary hearing.

(a) A provider that has been furnished a notice of amount of program reimbursement may request an intermediary hearing if it is dissatisfied with the intermediary's determination contained in the notice and the amount in controversy requirement described in § 405.1809 is met. The request must be in writing and be filed with the intermediary within 180 calendar days after the date of the notice. (See § 405.1835(c)). No other individual, entity, or party has the right to an intermediary hearing.

(b) The request must (1) identify the aspect(s) of the determination with which the provider is dissatisfied, and (2) explain why the provider believes the determination on these matters is incorrect, and (3) be submitted with any documentary evidence the provider considers necessary to support its position.

(c) Following the timely filing of the request for hearing, the provider may identify in writing, prior to the onset of the hearing proceedings, additional aspects of the determination with which it is dissatisfied and furnish any documentary evidence in support thereof. If such additional aspects are submitted, the hearing officer may postpone the hearing to allow for his examination of such additional aspects.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 39835, Sept. 1, 1983]

§ 405.1813 Failure to timely request an intermediary hearing.

If a provider requests an intermediary hearing on an intermediary's determination after the time limit prescribed in § 405.1811, the designated intermediary hearing officer or panel of hearing officers will dismiss the request and furnish the provider a written notice that explains the time limitation, except that for good cause shown, the time limit prescribed in § 405.1811 may be extended. However, an extension may not be granted if the extension request is filed more than 3 years after the date of the original notice of the intermediary determination.

[48 FR 39835, Sept. 1, 1983]

§ 405.1815 Parties to the intermediary hearing.

The parties to the intermediary hearing shall be the parties to the intermediary determination and any other entity determined by the intermediary to be a related organization of such provider. Said parties shall be given reasonable notice of the time, date, and place of such hearing. Neither the intermediary nor the Health Care Financing Administration are parties (see § 405.1819).

§ 405.1817 Hearing officer or panel of hearing officers authorized to conduct intermediary hearing; disqualification of officers.

The intermediary hearing provided for in § 405.1809 shall be conducted by a hearing officer or panel of hearing officers designated by the intermediary. Such hearing officer or officers shall be persons knowledgeable in the field of health care reimbursement. The hearing officer or officers shall not have had any direct responsibility for the program reimbursement determination with respect to which a request for hearing is filed; no hearing officer (or officers) shall conduct a hearing in a case in which he is prejudiced or partial with respect to any party, or where he has any interest in the matter pending for determination before him. Notice of any objection which a party may have with respect to a hearing officer shall be presented in writing to such officer by the objecting party at the party's earliest opportunity. The hearing officer shall consider the objection and shall, at his discretion, either proceed in the conduct of the hearing or withdraw. If the hearing officer does not withdraw, the objecting party may, after the hearing, present his objections to an executive official of the intermediary, who shall rule promptly on the objection.

§ 405.1819 Conduct of intermediary hearing.

The hearing shall be open to all parties thereto (see § 405.1815) and to representatives of the intermediary and of the Health Care Financing Administration (see § 405.1815). The hearing officer(s) shall inquire fully into all of the matters at issue and shall receive into evidence the testimony and any documents which are relevant and material to such matters. If the hearing officer(s) believes that there is relevant and material evidence available which has not been presented at the hearing, he (they) may, at any time prior to the mailing of notice of the decision, reopen the hearing record for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the hearing officer(s).

§ 405.1821 Prehearing discovery and other proceedings prior to the intermediary hearing.

(a) Prehearing discovery shall be permitted upon timely request of any party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the hearing officer(s).

(b) If, in the discretion of the hearing officer(s), the purpose of defining the issues more clearly would be served, the hearing officer(s) may schedule a prehearing conference. For this purpose, a single member of a panel of hearing officers, when such is the case, may be appointed to act for the panel with respect to prehearing activities.

§ 405.1823 Evidence at intermediary hearing.

Evidence may be received at the intermediary hearing even though inadmissible under the rules of evidence applicable to court procedure. The hearing officer(s) shall give the parties opportunity for submission and consideration of facts and arguments, and during the course of the hearing, should in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The hearing officer(s) shall render a final ruling on the admissibility of evidence.

§ 405.1825 Witnesses at intermediary hearing.

The hearing officer(s) may examine the witnesses and shall allow the parties and their representatives to do so. Parties to the proceedings may also cross-examine witnesses.

§ 405.1827 Record of intermediary hearing.

A complete recordation of the proceedings at the intermediary hearing shall be made and transcribed in all cases. It shall be made available to any party upon request. The record will not be closed until a decision (see § 405.1831) has been issued.

§ 405.1829 Authority of hearing officer(s) at intermediary hearing.

(a) The hearing officer(s) in exercising his authority must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with HCFA Rulings issued under the authority of the Administrator of the Health Care Financing Administration (see 42 CFR 401.108), and with the general instructions issued by the Health Care Financing Administration in accordance with the Secretary's agreement with the intermediary.

(b) The determination of a fiscal intermediary that no payment may be made under title XVIII of the Act for any expense incurred for items and services furnished to an individual because such items and services are excluded from coverage pursuant to section 1862 of the Act, 42 U.S.C. 1395y (see Subpart C of this part), shall not be reviewed by the hearing officer(s). Such determination shall be reviewed only in accordance with the applicable provisions of Subparts G and H of this part.

§ 405.1831 Intermediary hearing decision and notice.

The hearing officer(s) shall, on a timely basis, render a decision in writing based on the evidence in the record; such decision shall constitute the final determination of the intermediary. In such decision, he will cite applicable law, regulations, HCFA Rulings, and general instructions of the Health Care Financing Administration, as well as findings on all the matters in issue at the hearing. A copy of the decision will be mailed to all parties to the hearing at their last known addresses.

§ 405.1833 Effect of intermediary hearing decision.

The intermediary hearing decision provided for in § 405.1831 shall be final and binding upon all parties to the hearing unless such intermediary determination is revised in accordance with § 405.1885.

§ 405.1835 Right to Board hearing.

(a) *Criteria.* The provider (but no other individual, entity, or party) has a right to a hearing before the Board about any matter designated in § 405.1801(a)(1), if:

(1) An intermediary determination has been made with respect to the provider; and

(2) The provider has filed a written request for a hearing before the Board under the provisions described in § 405.1841(a)(1); and

(3) The amount in controversy (as determined in § 405.1839(a)) is $10,000 or more.

(b) *Prospective payment exceptions.* Except with respect to matters for which administrative or judicial review is not permitted as specified in § 405.1804, hospitals that are paid under the prospective payment system are entitled to hearings before the Board under this section if they otherwise meet the criteria described in paragraph (a) of this section.

(c) *Right to hearing based on late intermediary determination about reasonable cost.* Notwithstanding the provisions of paragraph (a)(1) of this section, the provider also has a right to a hearing before the Board if an intermediary's determination concerning the amount of reasonable cost reimbursement due a provider is not rendered within 12 months after receipt by the intermediary of a provider's perfected cost report or amended cost report (as permitted or as required to furnish sufficient data for purposes of making such determination—see § 405.1803(a)) provided such delay was not occasioned by the fault of the provider.

[48 FR 39835, Sept. 1, 1983]

§ 405.1837 Group appeal.

(a) *Criteria for group appeals.* Subject to paragraph (b) of this section, a group of providers may bring an appeal before the Board but only if—

(1) Each provider in the group is identified as one which would, upon the filing of a request for a hearing before the Board, but without regard to the $10,000 amount in controversy requirement, be entitled to a hearing under § 405.1835;

(2) The matters at issue involve a common question of fact or of interpretation of law, regulations or HCFA Rulings; and

(3) The amount in controversy is, in the aggregate, $50,000 or more.

(b) *Providers under common ownership or control.* Effective April 20, 1983, any appeal filed by providers that are under common ownership or control must be brought by the providers as a group appeal in accordance with the provisions of paragraph (a) of this section with respect to any matters involving an issue common to the providers and for which the amount in controversy is, in the aggregate, $50,000 or more (see § 405.1841(a)(2)). A single provider involved in a group appeal that also wishes to appeal issues that are not common to the other providers in the group must file a separate hearing request (see § 405.1841(a)(1)) and must separately meet the requirements in § 405.1811 or § 405.1835, as applicable.

[48 FR 39836, Sept. 1, 1983]

§ 405.1839 Amount in controversy.

(a) *Single appeals.* The $1,000 amount in controversy required under § 405.1809 for an intermediary hearing and the $10,000 amount in controversy required under § 405.1835 for a Board hearing is, as applicable to the matters for which the provider has requested a hearing, the combined total of the amounts computed as follows:

(1) *Providers under prospective payment.* For providers that are paid under the prospective payment system, by deducting—

(i) The total of the payment due the provider on other than a reasonable cost basis under the prospective payment system from the total amount that would be payable after a recomputation that takes into account any exclusion, exception, adjustment, or additional payment denied the provider under Part 412 of this chapter, as applicable;

(ii) The total of the payment due the provider on a reasonable cost basis under the prospective payment system from the total reimbursable costs claimed by the provider; and

(iii) The adjusted total reimbursable costs due the provider on a reasonable cost basis under other than the prospective payment system from the total reimbursable costs claimed by the provider.

(2) *Providers not under prospective payment.* For providers that are not paid under the prospective payment system, by deducting the adjusted total reimbursable program costs due the provider on a reasonable cost basis from the total reimbursable costs claimed by the provider.

(b) *Group appeals.* The $50,000 amount in controversy required under § 405.1837 for group appeals to the Board is, as applicable to the common matters for which the group of providers have requested a hearing, the combined total of the amounts computed as follows:

(1) *Providers under prospective payment.* For providers that are paid under the prospective payment system, by deducting—

(i) The total of the payment due the providers (in the aggregate) on other than a reasonable cost basis under the prospective payment system from the total amount that would be payable to the providers (in the aggregate) after a recomputation that takes into account any applicable exception, exclusion, adjustment, or additional payment denied the providers under Part 412 of this chapter.

(ii) The total of the payment due the providers (in the aggregate) on a reasonable cost basis under the prospective payment system from the total reimbursable costs claimed in the aggregate by the providers; and

(iii) The adjusted total reimbursable costs due the providers (in the aggregate) on a reasonable cost basis under other than the prospective payment system from the total reimbursable costs claimed in the aggregate by the providers.

(2) *Providers not under prospective payment.* For providers that are not paid under the prospective payment system, by deducting the adjusted total reimbursable program costs due the providers (in the aggregate) on a reasonable cost basis from the total reimbursable costs claimed in the aggregate by the providers.

[49 FR 323, Jan. 3, 1984]

§ 405.1841 Time, place, form, and content of request for Board hearing.

(a) *General requirements.* (1) The request for a Board hearing must be filed in writing with the Board within 180 days of the date the notice of the intermediary's determination was mailed to the provider or, where notice of the determination was not timely rendered, within 180 days after the expiration of the period specified in § 405.1835(c). Such request for Board hearing must identify the aspects of the determination with which the provider is dissatisfied, explain why the provider believes the determination is incorrect in such particulars, and be accompanied by any documenting evidence the provider considers necessary to support its position. Prior to the commencement of the hearing proceedings, the provider may identify in writing additional aspects of the intermediary's determination with which it is dissatisfied and furnish any documentary evidence in support thereof.

(2) Effective April 20, 1983, any request for a Board hearing by providers that are under common ownership or control (see § 413.17 of this chapter) must be brought by the providers as a group appeal (see § 405.1837(b)) with respect to any matters at issue involving a question of fact or of interpretation of law, regulations, or HCFA Rulings common to the providers and for which the amount in controversy is $50,000 or more in the aggregate. If a group appeal is filed, the provider seeking the appeal must be separately identified in the request for hearing, which must be prepared and filed consistently with the requirements of paragraph (a)(1) of this section.

(b) *Extension of time limit for good cause.* A request for a Board hearing filed after the time limit prescribed in paragraph (a) of this section shall be dismissed by the Board, except that for good cause shown, the time limit may be extended. However, no such extension shall be granted by the Board if such request is filed more than 3 years after the date the notice of the intermediary's determination is mailed to the provider.

[48 FR 39836, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§ 405.1842 Expediting Board proceedings.

(a) *Basis and purpose.* This section implements section 1878(f)(1) of the Social Security Act, as amended by section 955 of Pub. L. 96-499 (42 U.S.C. 1395oo(f)(1)). The amendment provides an opportunity for providers to obtain expedited administrative review when the Board determines that it does not have the authority to decide a question of law, regulation, or HCFA Ruling relevant to the case (see § 405.1867).

(b) *Basic rule.* (1) Except as provided in paragraph (b)(4) of this section, a provider may submit a written request to the Board, with supporting documentation, to determine whether the Board has the authority to decide a question of law, regulations, or HCFA Rulings relevant to and controlling upon an issue to be reviewed by the Board. The Board is required to make an expedited review determination in writing, either denying or granting the request, within 30 days after the date of receipt of the request, as defined in paragraph (1) of this section. The Board may also issue a determination on its own motion that it lacks authority to decide a question of law, regulations or HCFA Rulings.

(2) The Board must determine that the provider (including each provider in a group appeal) is entitled to a hearing under section 1878(a) of the Act before making the determination described in paragraph (b)(1) of this section. Thus, the provider must file (or have already filed) a written request for a Board hearing that meets the requirements in § 405.1841. The information and documentation required with respect to the filing of a request for a hearing is used by the Board to determine jurisdiction under section 1878(a) of the Act.

(3) A provider's request for an expedited review determination cannot be considered to be filed with the Board, nor can the 30-day time period during which the Board is required to make an expedited review determination begin, until such time as the Board accepts jurisdiction of the case.

(4) Proceedings conducted by the Board under an authority other than section 1878(a) of the Act and §§ 405.1835 through 405.1873 of this subpart are not hearings for purposes of this section and are not subject to the expedited Board proceedings set forth in this section. For example, proceedings concerning reimbursement for capital expenditures conducted under section 1122(f) of the Act and § 405.1890 of this subpart are not hearings for purposes of this section. (Section 1122(f) specifically bars any administrative or judicial review.)

(c) *"Own motion" review.* If the Board is considering issuing a determination on its own motion that it lacks the authority to decide a question of law, regulations, or HCFA Rulings, it will notify the provider and intermediary of its proposed determination and allow them a reasonable period of time to file evidence or arguments either to support or oppose the proposed determination.

(d) *Provider requests.* (1) If a provider seeks an expedited Board proceeding, it must—(i) File its appropriately documented request in writing with the Board; and

(ii) Send a copy of the request and documentation simultaneously to the intermediary.

(2) The request to the Board for an expedited review determination must—(i) Identify the issues and the controlling law, regulation or HCFA Ruling for which the Board is to make a determination;

(ii) Allege and demonstrate that there are no factual issues in dispute;

(iii) Contain an explanation of why the provider believes the Board cannot decide the legal issue or issues that are in dispute; and

(iv) Include all other information or details that support the request.

(3) If the information in the provider request is insufficient for the Board to determine whether it has the authority to decide an issue, the Board will request more information from the provider. Such a request will affect the 30-day time limit as provided in paragraph (i) of this section. If the provider does not send more information or sends inadequate information, the Board will determine that it has the authority to decide the issue and will begin the regular procedure for a hearing.

(e) *Intermediary participation* (1). After receiving a copy of the provider's request for an expedited review determination, the intermediary may send comments to the Board on the provider's request and supporting documentation. The intermediary will send a copy of its comments to the provider simultaneously.

(2) If the intermediary's comments raise questions about the provider's request for expedited review, the Board may request additional information from the provider as provided in paragraph (d)(3) of this section.

(f) *Criteria for a Board determination.* The Board will review all documentation forwarded by the provider and the intermediary relevant to the request for a Board determination concerning the Board's authority to decide an issue. In its review, the Board will consider—

(1) The controlling facts in the case;

(2) The applicability of law, regulations, or HCFA rulings;

(3) Whether there are factual issues for the Board to resolve; and

(4) Whether there are legal issues within the authority of the Board to decide.

(g) *Board determination.* (1) Within 30 days after the date of receipt (as defined in paragraph (i) of this section) of a provider's request and all necessary documentation the Board will issue a determination concerning its authority to decide the question of law, regulations, or HCFA Rulings relevant to the issues identified by the provider in its request.

(2) If there are factual or legal issues in dispute on an issue within the authority of the Board to decide, the Board will not make an expedited review determination on the particular issue but will proceed with a hearing. The Board has the authority to decide when two or more issues are sufficiently related to preclude separation for purposes of an expedited review determination on one or more of them and a hearing on the other or others.

(3) The Board will promptly notify the provider in writing of its determination and will send a copy of the determination to the intermediary.

(4) The Board's determination concerning its authority or its lack of a determination is not subject to the Secretary's review under § 405.1875.

(h) *Effect of a Board decision.* (1) The Board's determination, issued on its own motion or at the request of a provider, that it lacks authority to decide a question of law, regulations or HCFA Rulings is a final decision permitting a provider to seek judicial review with respect to the matter or matters in controversy contained in the determination, within 60 days of the date of the Board's determination.

(2) After the Board has determined that it does not have the authority to decide an issue, the provider will not be granted a hearing on the same issue.

(3) If the Board fails to issue an expedited review determination within 30 days of the date of receipt of a complete request (as determined under paragraph (i) of this section), the provider may, within 60 days from the end of that period, seek judicial review of the matters for which it requested the Board's determination.

(4) If the Board fails to make an expedited review determination within the required 30 days, it will begin regular hearing procedures as though it has the authority to decide the issue.

(5) If the provider seeks judicial review because the Board fails to make a determination as provided in paragraph (g)(1) of this section, it should notify the Board at the time it files for judicial review. The Board will not hold a hearing, even if one has been scheduled, on the matter or matters for which the provider is seeking judicial review.

(6) The Board's determination does not affect the right of the provider to a Board hearing for issues for which

the provider did not request expedited review, or for which the Board determines it does have the authority to decide, or for which the Board did not make a determination and the provider did not request judicial review.

(i) *Date of receipt.* For purposes of this section, the date of receipt of the provider's request is the later of—

(1) The actual date of receipt by the Board of the information required under paragraph (d)(2) of this section, or of additional information requested by the Board under paragraph (d)(3) of this section, whichever the Board receives later; or

(2) The date indicated on the Board's written notification to the provider that the Board has accepted jurisdiction of the case.

(j) *Examples.* Below are examples showing when a provider may expect to receive an expedited review determination, in relation to various circumstances affecting its request for the determination.

(1) The provider requests a hearing and expedited review at or about the same time. If all information is complete, the Board could send notification that it has accepted jurisdiction of the case and the expedited review determination simultaneously.

(2) The provider requests both a hearing and an expedited review determination, and supplies complete information. The Board accepts jurisdiction but, for example, because of the complexity of the case, the Board makes its expedited review determination within 30 days after it has accepted jurisdiction.

(3) The provider requests both a hearing and an expedited review determination, but the request for a hearing does not contain enough information for the Board to determine jurisdiction. The Board would request more information to determine jurisdiction and would make its expedited review determination within 30 days after it has accepted jurisdiction.

(4) The provider requests both a hearing and an expedited review determination, but does not send enough information for the Board to make an expedited review determination. Assuming the Board accepts jurisdiction, the Board would request more information about the request for expedited review and make its determination within 30 days after it receives the additional information.

(5) The provider requests an expedited review determination after the Board has accepted jurisdiction. The Board would make its determination within 30 days after receipt of an appropriately documented request for an expedited review determination.

[47 FR 31690, July 22, 1982, as amended at 48 FR 22925, May 23, 1983]

§ 405.1843 Parties to Board hearing.

(a) The parties to the Board hearing shall be the provider, the intermediary (including the Health Care Financing Administration when acting directly as intermediary) that rendered the determination being appealed (see § 405.1833), and any other entity found by the intermediary to be a related organization of such provider.

(b) Except as provided in paragraph (a), neither the Secretary nor the Health Care Financing Administration may be made a party to the hearing. However, the Board may call as a witness any employee or officer of the Department of Health and Human Services having personal knowledge of the facts and the issues in controversy in a hearing pending before the Board and may call as a consultant to the Board in connection with any such hearing any individual designated by the Secretary for such purpose. (See § 405.1863.)

§ 405.1845 Composition of Board.

(a) The Board will consist of five members appointed by the Secretary. All shall be knowledgeable in the field of cost reimbursement. At least one shall be a certified public accountant. Two Board members shall be representative of providers of services.

(b) The term of office for Board members shall be 3 years, except that initial appointments may be for such shorter terms as the Secretary may designate to permit staggered terms of office. No member shall serve more than two consecutive 3-year terms of office. The Secretary shall have the authority to terminate a Board member's term of office for good cause.

(c) One member of the Board shall be designated by the Secretary as Chairman thereof and shall coordinate and direct the administrative activities of the Board, and shall have such other authority which may be granted to him by the Board.

(d) A quorum shall be required for the rendering of Board decisions. Three members, at least one of whom is representative of providers of services, shall be required to constitute a quorum. The Chairman of the Board, with approval of the provider, may designate one or more Board members to conduct any hearing and to prepare a recommended decision (where less than a quorum conducts the hearing). (See § 405.1869.)

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.1847 Disqualification of Board members.

No Board member shall join in the conduct of a hearing in a case in which he is prejudiced or partial with respect to any party or in which he has any interest in the matter pending for decision before him. Notice of any objection which a party may have with respect to a Board member shall be presented in writing to such Board member by the objecting party at its earliest opportunity. The Board member shall consider the objection and shall, in his discretion, either proceed to join in the conduct of the hearing or withdraw. If he does not withdraw, the objecting party may petition the Board, presenting its objection and reasons therefor, and be entitled to a ruling thereon before the hearing can proceed.

§ 405.1849 Establishment of time and place of hearing by the Board.

The Board shall fix the time and place for the hearing and shall mail written notice thereof to the parties at their last known addresses, not less than 30 days prior to the scheduled time. Either on its own motion or for good cause shown by a party, the Board may, as appropriate, reschedule, adjourn, postpone, or reopen the hearing, provided that reasonable written notice is given to the parties.

§ 405.1851 Conduct of Board hearing.

The Board hearing shall be open to the parties, to representatives of the Health Care Financing Administration, and to such other persons as the Board deems necessary and proper. The Board shall inquire fully into all of the matters at issue and shall receive into evidence the testimony of witnesses and any documents which are relevant and material to such matters. If the Board believes that there is relevant and material evidence available which has not been presented at the hearing, it may at any time prior to the mailing of notice of the decision, reconvene the hearing for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the Board.

§ 405.1853 Prehearing discovery and other proceedings prior to the Board hearing.

(a) Upon notification that a request for Board hearing has been filed, the intermediary shall forthwith review the materials submitted by the provider in accordance with § 405.1841. Simultaneously, the intermediary shall review the information which formed the basis for its determination of the amount of program reimbursement. Based on the findings of such review, the intermediary shall expeditiously attempt to join with the provider in written stipulations setting forth the issues that said review has resolved and designating the issues that remain for Board resolution. Having obtained such stipulations and being satisfied that no further agreements can be negotiated, the intermediary shall ensure that all available documentary evidence in support of each party's position is part of the record. Such evidence will ordinarily include a position paper from the provider, a position paper from the intermediary, and any documents which support the issues addressed in the stipulations. These materials, in addition to all relevant documents which formed the basis for its determination of the amount of program reimbursement, shall be forwarded to the Board within 60 days after the date of the provider's request for Board review.

(b) Prehearing discovery shall be permitted upon timely request of a party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the Board. The Board's order on all discovery matters shall be final.

(c) If, in the discretion of the Board, the purpose of defining the issues more clearly would be served, the Board may schedule a prehearing conference. For this purpose, a single member of the Board may be appointed to act for the Board with respect to prehearing activities.

§ 405.1855 Evidence at Board hearing.

Evidence may be received at the Board hearing even though inadmissible under the rules of evidence applicable to court procedure. The Board shall give the parties opportunity for submission and consideration of facts and arguments and during the course of the hearing should, in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The Board shall render a final ruling on the admissibility of evidence.

§ 405.1857 Subpoenas.

When reasonably necessary for the full presentation of a case, the Board may, either upon its own motion or upon the request of a party, issue subpoenas for the attendance and testimony of witnesses and for the production of books, records, correspondence, papers, or other documents which are relevant and material to any matter in issue at the hearing. Parties who desire the issuance of a subpoena shall, not less than 10 days prior to the time fixed for the hearing, file with the Board a written request therefor, designating the witnesses or documents to be produced, and describing the address, or location thereof with sufficient particularity to permit such witnesses or documents to be found. The request for a subpoena shall state the pertinent facts which the party expects to establish by such witnesses or documents and whether such facts could be established by other evidence without the use of a subpoena. Subpoenas, as provided for above, shall be issued in the name of the Board, and the Health Care Financing Administration shall assume the cost of the issuance and the fees and mileage of any witness so subpoenaed, as provided in section 205(d) of the Act, 42 U.S.C. 405(d).

§ 405.1859 Witnesses.

Witnesses at the hearing shall testify under oath or affirmation, unless excused by the Board for cause. The Board may examine the witnesses and shall allow the parties or their representatives to do so. Parties to the proceeding may also cross-examine witnesses.

§ 405.1861 Oral argument and written allegations.

The parties, upon their request, shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements of allegations as to facts or law. Copies of any brief or other written statement shall be filed in sufficient number that they may be made available to all parties and to the Health Care Financing Administration.

§ 405.1863 Administrative policy at issue.

Where a party to the Board hearing puts into issue an administrative policy which is interpretative of the law or regulations, the Board will promptly notify to the Health Care Financing Administration.

§ 405.1865 Record of Board hearing.

A complete record of the proceedings at the hearing shall be made and transcribed in all cases. It shall be made available to the parties upon request. The record will not be closed until a decision has been issued.

§ 405.1867 Sources of Board's authority.

In exercising its authority to conduct the hearings described herein, the Board must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as HCFA Rulings issued under the authority of the Administrator of the Health Care Financing Administration (see § 401.108 of this subchapter). The Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by HCFA.

[48 FR 22925, May 23, 1983]

§ 405.1869 Scope of Board's decision-making authority.

The Board shall have the power to affirm, modify, or reverse a determination of an intermediary with respect to a cost report and to make any other modifications on matters covered by such cost report (including modifications adverse to the provider or other parties) even though such matters were not considered in the intermediary's determination. The opinion of the majority of those Board members deciding the case will constitute the Board's decision.

§ 405.1871 Board hearing decision and notice.

(a) The Board shall, as soon as practicable after the conclusion of its hearing, render a written decision based upon the record made at such hearing, the record established in support of the determination of the intermediary (see § 405.1803), and such other evidence as may be obtained or received by the Board. Such Board decision shall be supported by substantial evidence when the record of the Board hearing is viewed as a whole and shall cite applicable law, regulations, and HCFA Rulings. A copy of the decision shall be mailed to all parties to the hearing at their last known addresses and, at the same time, to the Administrator and HCFA.

(b) The decision of the Board provided for in paragraph (a) of this section shall be final and binding upon all parties to the hearing before the Board unless it is reviewed by the Secretary in accordance with § 405.1875, or revised in accordance with § 405.1885.

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 45773, Oct. 7, 1983]

§ 405.1873 Board's jurisdiction.

(a) *Board decides jurisdiction.* The Board decides questions relating to its jurisdiction to grant a hearing, including (1) the timeliness of an intermediary determination (see § 405.1835(c)), and (2) the right of a provider to a hearing before the Board when the amount in controversy is in issue (see §§ 405.1835(a)(3) and 405.1837).

(b) *Matters not subject to board review.* (1) The determination of a fiscal intermediary that no payment may be made under title XVIII of the Act for any expenses incurred for items and services furnished to an individual because such items and services are excluded from coverage pursuant to section 1862 of the Act, 42 U.S.C. 1395y (see Subpart C of this part), may not be reviewed by the Board. (Such determination shall be reviewed only in accordance with the applicable provisions of Subpart G or H of this part.)

(2) The Board may not review certain matters affecting payments to hospitals under the prospective payment system as provided in § 405.1804.

[48 FR 39836, Sept. 1, 1983]

§ 405.1875 Administrator's review.

(a) *General rule.* (1) Except for a Board determination under § 405.1842 that it lacks the authority to decide an issue, the Administrator, at his or her discretion, may review any final decision of the Board, including a decision under § 405.1873 about the Board's jurisdiction to grant a hearing. The Administrator may exercise this discretion on his or her own motion, in response to a request from a party to a Board hearing or in response to a request from HCFA.

(2) The Office of the Attorney Advisory will examine the Board's decisions, the requests made by a party or HCFA and any submission made in accordance with the provisions of this section in order to assist the Administrator in deciding whether to exercise this review authority.

(b) *Request for review.* A party or HCFA requesting the Administrator to review a Board decision must file a written request with the Administrator within 15 days of the receipt of the Board decision.

(c) *Criteria for deciding whether to review.* In deciding whether to review a Board decision, either on his or her own motion or in response to a request from a party to the hearing or HCFA, the Administrator will normally consider whether it appears that:

(1) The Board made an erroneous interpretation of law, regulation or HCFA Ruling;

(2) The Board's decision is not supported by substantial evidence; or

(3) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to the issuance of a HCFA Ruling or other directive needed to clarify a statutory or regulatory provision;

(4) The Board has incorrectly assumed or denied jurisdiction or extended its authority to a degree not provided for by statute, regulation or HCFA Ruling; and

(5) The decision of the Board requires clarification, amplification, or an alternative legal basis for the decision.

(d) *Decision to review.* (1) Whether or not a party or HCFA has requested review, the Administrator will promptly notify the parties and HCFA whether he or she has decided to review a decision of the Board and, if so, will indicate the particular issues he or she will consider.

(2) The Administrator may decline to review a case or any issue in a case even if a party has filed a written request for review under paragraph (b) of this section.

(e) *Written submissions.* (1) Within 15 days of receipt of a notice that the Administrator has decided to review a Board decision, a party or HCFA may submit to the Administrator, in writing:

(i) Proposed findings and conclusions;

(ii) Supporting views or exceptions to the Board decision;

(iii) Supporting reasons for the exceptions and proposed findings; and

(iv) A rebuttal of the other party's request for review or other submissions already filed with the Administrator.

(2) These submissions shall be limited to issues the Administrator has decided to review and confined to the record of the Board hearing.

(3) A party or HCFA, within 15 days of receipt of a notice that the Administrator has decided to review a decision, may also request that the decision be remanded and state reasons for doing so. Reasons for a request to remand may include new, substantial evidence concerning—

(i) Issues presented to the Board; and

(ii) New issues that have arisen since the case was presented to the Board.

(4) A copy of any written submission made under this paragraph shall be sent simultaneously to each other party to the Board hearing and to HCFA, if HCFA has previously—

(i) Requested that the Administrator review a Board decision or filed a written submission in response to a party's request for review.

(ii) Responded to a party's request for review; or

(iii) Submitted material after the Administrator has announced that he or she will review a Board decision.

(f) *Ex parte communications prohibited.* All communications from any of the parties or HCFA about a Board decision being reviewed by the Administrator must be in writing and must contain a certification that copies have been served on the parties and HCFA, as appropriate. The Administrator will not consider any communication that does not meet these requirements or is not submitted within the required time limits.

(g) *Administrator's decision.* (1) If the Administrator has notified the parties and HCFA that he or she has decided to review a Board decision, the Administrator will affirm, reverse, modify or remand the case.

(2) The Administrator will make this decision within 60 days after the provider received notification of the Board decision and will promptly mail a copy of the decision to each party and to HCFA.

(3) Any decision other than to remand will be confined to—

(i) The record of the Board, as forwarded by the Board;

(ii) Any materials submitted under paragraphs (b) or (e) of this section; and

(iii) Generally known facts that are not subject to reasonable dispute.

(4) The Administrator may rely on prior decisions of the Board, the Administrator and the courts, and other applicable law, whether or not cited by the parties and HCFA.

(h) *Remand.* (1) A remand to the Board by the Administrator vacates the Board's decision.

(2) The Administrator may direct the Board to take further action with respect to the development of additional facts or new issues, or to consider the applicability of laws or regulations other than those considered by the Board. The following are not acceptable bases for remand—

(i) Presentation of evidence existing at the time of the Board hearing that was known or reasonably could have been known;

(ii) Introduction of a favorable court case that was either not available in print at the time of the Board hearing or was decided after the Board hearing;

(iii) Change of a party's representation before the Board;

(iv) Presentation of an alternative legal basis concerning an issue in dispute; or

(v) Attempted retraction of a waiver of a right made before or at the Board hearing.

(3) After remand, the Board will take the action requested in the remand action and issue a new decision.

(4) The new decision will be final unless the Administrator reverses, affirms, modifies, or again remands the decision in accordance with the provisions of the section.

[48 FR 45773, Oct. 7, 1983]

§ 405.1877 Judicial review.

(a) *General rule.* Section 1878(f) of the Act permits a provider to obtain judicial review of a final decision of the Board, or of a reversal, affirmation, or modification by the Administrator of a Board decision, by filing a civil action pursuant to the Federal Rules of Civil Procedure within 60 days of the date on which the provider received notice of—

(1) A final decision by the Board; or

(2) Any reversal, affirmance, or modification by the Administrator.

The Board's decision is not final if the Administrator reverses, affirms or modifies the decision within 60 days of the date on which the provider received notice of the decision.

(b) *Administrator declines to review a Board decision.* If the Administrator declines to review a Board decision, the provider must file its appeal within 60 days of receipt of the decision of the Board.

(c) *Administrator does not act after reviewing a Board decision.* If the Administrator notifies the parties that he or she has decided to review a Board decision and then does not make a decision within the 60 days allotted for his or her review, this subsequent inaction constitutes an affirmance allowing a provider an additional 60 days in which to file for judicial review, beginning with the date the Administrator's time expires for taking action under § 405.1875(g)(2).

(d) *Matters not subject to judicial review.* Certain matters affecting payments to hospital under the prospective payment system are not subject to judicial review, as provided in section 1886(d)(7) of the Act and § 405.1804.

(e) *Group appeals.* Any action under this section by providers that are under common ownership or control (see § 413.17 of this chapter) must be brought by the providers as a group with respect to any matter involving an issue common to the providers.

(f) *Venue for appeals.* An action for judicial review must be brought in the District Court of the United States for the judicial district in which the provider is located (or, effective April 20, 1983, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia. Effective April 20, 1983, any action for judicial review by providers under common ownership or control (§ 413.17 of this chapter), must be brought by such providers as a group with respect to any matter involving an issue common to the providers.

(g) *Service of process.* Process must be served as described under 45 CFR Part 4.

[48 FR 39836, Sept. 1, 1983, as amended at 48 FR 45774, Oct. 7, 1983; 51 FR 34793, Sept. 30, 1986]

§ 405.1881 Appointment of representative.

A provider or other party may be represented by legal counsel or any other person it appoints to act as its representative at the proceedings, conducted in accordance with §§ 405.1819 and 405.1851.

§ 405.1883 Authority of representative.

A representative appointed by a provider or other party may accept or give on behalf of the provider or other party any request or notice relative to any proceeding before a hearing officer or the Board. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to a request for an intermediary hearing or a Board hearing made in accordance with §§ 405.1811, 405.1835, or § 405.1837 to the same extent as the party he represents. Notice to a provider or other party of any action, determination, or decision, or a request for the production of evidence by a hearing officer or the Board sent to the representative of the provider or other party shall have the same force and effect as if it had been sent to the provider or other party.

§ 405.1885 Reopening a determination or decision.

(a) A determination of an intermediary, a decision by a hearing officer or panel of hearing officers, a decision by the Board, or a decision of the Secretary may be reopened with respect to findings on matters at issue in such determination or decision, by such intermediary officer or panel of hearing officers, Board, or Secretary, as the case may be, either on motion of such intermediary officer or panel of hearing officers, Board, or Secretary, or on the motion of the provider affected by such determination or decision to revise any matter in issue at any such proceedings. Any such request to reopen must be made within 3 years of the date of the notice of the intermediary or Board hearing decision, or where there has been no such decision, any such request to reopen must be made within 3 years of the date of notice of the intermediary determination. No such determination or decision may be reopened after such 3-year period except as provided in paragraphs (d) and (e) of this section.

(b) A determination or a hearing decision rendered by the intermediary shall be reopened and revised by the intermediary if, within the aforementioned 3-year period, the Health Care Financing Administration notifies the intermediary that such determination or decision is inconsistent with the applicable law, regulations, or general instructions issued by the Health Care Financing Administration in accordance with the Secretary's agreement with the intermediary.

(c) Jurisdiction for reopening a determination or decision rests exclusively with that administrative body that rendered the last determination or decision.

(d) Notwithstanding the provisions of paragraph (a) of this section, an intermediary determination or hearing decision, a decision of the Board, or a decision of the Secretary shall be reopened and revised at any time if it is established that such determination or decision was procured by fraud or similar fault of any party to the determination or decision.

(e) Paragraphs (a) and (b) of this section apply to determinations on cost reporting periods ending on or after December 31, 1971. (See § 405.1801(c).) However, the 3-year period described shall also apply to determinations with respect to cost reporting periods ending prior to December 31, 1971, but only if the reopening action was undertaken after May 27, 1972 (the effective date of regulations which, prior to the publication of this Subpart R, governed the reopening of such determinations).

§ 405.1887 Notice of reopening.

(a) All parties to any reopening described above shall be given written notice of the reopening. When such reopening results in any revision in the prior decision notice of said revision or revisions will be mailed to the parties with a complete explanation of the basis for the revision or revisions. Notices of reopenings by the Board shall also be sent to the Secretary.

(b) In any such reopening, the parties to the prior decision shall be allowed a reasonable period of time in which to present any additional evidence or argument in support of their position.

§ 405.1889 Effect of a revision.

Where a revision is made in a determination or decision on the amount of program reimbursement after such determination or decision has been reopened as provided in § 405.1885, such revision shall be considered a separate and distinct determination or decision to which the provisions of §§ 405.1811, 405.1835, 405.1875 and 405.1877 are applicable. (See § 405.1801(c) for applicable effective dates.)

§ 405.1890 Appeals from a determination under section 1122 of the Act.

(a) *Right to an appeal.* Any provider or person dissatisfied with a determination under section 1122 of the Act, 42 U.S.C. 1320a-1, other than a determination of amounts of reimbursement to be excluded, may request a reconsideration of such determination as provided for in 42 CFR 100.108(d). In addition, any provider or person may appeal a determination disallowing costs attributable to a nonapproved capital expenditure in accordance with applicable provisions in this Subpart R, subject to the exceptions in paragraphs (b), (c), (d) and (e) of this section.

(b) *Amount in issue is less than $10,000.* A determination of exclusion under section 1122 of the Act of an amount of less than $10,000 may be appealed to an intermediary's hearing officer or panel of hearing officers, using the mechanisms in §§ 405.1809-405.1833 and §§ 405.1885-405.1889, as applicable, except that:

(1) There is no requirement that the amount in issue disallowed under section 1122 of the Act be at least $1,000; and

(2) The period within which the provider may request review shall be 6 months, rather than the period described in § 405.1811(a).

(c) *Amount in issue is $10,000 or more.* A determination of exclusion under section 1122 of the Act of an amount of $10,000 or more (or with respect to a particular cost report, exclusion of an amount of less than $10,000, provided that the total amount in issue with respect to such cost report exceeds $10,000) may be appealed to the Provider Reimbursement Review Board, using the mechanism in §§ 405.1835 through 405.1889, except that:

(1) The period within which the provider may request review shall be 6 months, rather than the period described in § 405.1841(a); and

(2) Paragraph (a)(4) of § 405.1801 and § 405.1877 shall not apply to a determination of exclusion under section 1122 of the Act.

(d) *Other administrative review.* Except as provided in paragraphs (b) and (c) of this section, there is no administrative review of any determination of exclusion of costs under the authority of section 1122 of the Act.

(e) *Judicial review.* As provided in section 1122(f) of the Act and paragraph (c)(2) of this section, there is no judicial review of any determination made under the authority of section 1122.

[40 FR 32744, Aug. 4, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

Subparts S and T—[Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in § 405.2101, and general definitions are contained in § 405.2102. The provisions of §§ 405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

[51 FR 30361, Aug. 26, 1986]

§ 405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utlization of ESRD treatment resources while maintaining or improving the quality of care;

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and

(d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

[43 FR 48950, Oct. 19, 1979]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

Dialysis. A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of "ESRD service"). Such facilities are:

(a) *Renal Transplantation Center.* A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

(b) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(c) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(d) *Self-dialysis unit.* A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(e) *Special purpose renal dialysis facility.* A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(a) *Transplantation service.* A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

(b) *Dialysis service*—(1) *Inpatient dialysis.* Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) *Outpatient dialysis.* Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis.* Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis.* Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis.* Dialysis performed by an appropriately trained patient at home.

(c) *Self-dialysis and home dialysis training.* A program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through "agreements" or "arrangements").

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential donor organ and a potential organ transplant recipient.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (MCE). Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by HCFA.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Organ procurement. The process of acquiring donor kidneys. (See definition of *Organ procurement organization* in § 485.302 of this chapter.)

(a) Harvesting of donated kidneys;

(b) Preservation of donated kidneys;

(c) Transportation of donated kidneys; and

(d) Maintenance of a system to locate prospective recipients for harvested organs.

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) Chief executive officer. A person who:

(1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(2) Is a registered nurse or physician director as defined in this definition; or

(3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) *Dietitian.* A person who: (1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) *Medical record practitioner.* A person who:

(1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.

(2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or

(3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American Medical Record Association under its requirements in effect June 3, 1976.

(d) *Nurse responsible for nursing service.* A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process;

(3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) *Physician-director.* A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;

(3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) *Social worker.* A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice

at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.

(g) *Transplantation surgeon.* A person who:

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988]

§ 405.2110 Designation of ESRD networks.

HCFA designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* HCFA will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in § 405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§ 405.2111 [Reserved]

§ 405.2112 ESRD network organizations.

HCFA will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to HCFA an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

(i) Self-care;

(ii) Transplants; and

(iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or HCFA, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

§ 405.2113 Medical review board.

(a) *General.* The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members.* (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§ 405.2114 [Reserved]

§ 405.2120 Minimal utilization rates: general.

Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) authorizes the Secretary to limit reimbursement for ESRD care to those facilities which meet such requirements as the Secretary may prescribe, including minimal utilization rates for covered procedures. The minimal utilization rates, which are explained and specified in §§ 405.2121-405.2130, pertain to dialyses and transplantations. These utilization rates may be changed from time to time in accordance with program experience, and such changes will be published as amendments to these regulations.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2121 Basis for determining minimal utilization rates.

In developing minimal utilization rates, the Secretary takes into account the performance of ESRD facilities, the availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:

(a) Information on the geographic distribution of ESRD patients and facilities;

(b) Information on quality of care; and

(c) Information on operational and management efficiency.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept 30, 1977, and amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2122 Types and duration of classification according to utilization rates.

An ESRD facility that meets all the other conditions for coverage of ESRD services will be classified according to its utilization rate(s) as follows: Unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see § 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent classification occurs. (See § 405.2123 for reporting requirements; § 405.2124 for method of calculating rates: § 405.2130 for specific standards.)

(a) *Initial classification.* (1) An ESRD facility that has not previously participated in the ESRD program will be granted conditional status if it submits a written plan, detailing how it will achieve the utilization rates for conditional status by the end of the second calendar year of its operation under the ESRD program, and the rates required for unconditional status by the end of its fourth calendar year of operation.

(2) The ESRD facility's performance will be evaluated at the end of the first calendar year to ascertain whether it is properly implementing the plan.

(b) *Exception status.* (1) A renal dialysis center or a renal dialysis facility that does not meet the minimal utilization rate for unconditional or conditional status may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage under this subpart;

(ii) It is unable to meet the minimal utilization rate because it lacks a sufficient number of patients and is located in an area without a sufficient population base to support a center or facility which would meet the rate; and

(iii) Its absence would adversely affect the achievement of ESRD program objectives.

(2) A hospital that furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under this subpart, but does not meet the utilization standards prescribed in § 405.2130(a), may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage as a renal transplantation center;

(ii) The surgery is performed under the direct supervision of a qualified transplantation surgeon (§ 405.2102) who is also performing renal transplantation surgery at an approved renal transplantation center that is primarily oriented to adult nephrology;

(iii) It has an agreement, with the other hospital serviced by the surgeon, for sharing limited resources that are needed for kidney transplantation; and

(iv) There are pediatric patients who need the surgery and who cannot obtain it from any other hospital located within a reasonable distance.

[43 FR 48951, Oct. 19, 1978, as amended at 45 FR 58124, Sept. 2, 1980; 51 FR 30362, Aug. 26, 1986]

§ 405.2123 Reporting of utilization rates for classification.

Each facility must submit to HCFA an annual report on its utilization rates.

(a) Each hospital furnishing renal transplantation service must report both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.

(b) Each hospital or nonhospital facility furnishing dialysis service must report the number of dialysis stations it had operating and the total number of dialyses performed during both the most recent year of operation and each of the preceding 2 calendar years. For dialyses performed on or after October 1, 1978, the report must separately identify, by type of ESRD service, the total number of dialyses performed at each station.

[43 FR 48951, Oct. 19, 1978]

§ 405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status.

For purposes of classification the Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.

§ 405.2130 Condition: Minimal utilization rates.

The ESRD facility meets the applicable minimal utilization rate(s) indicated below for unconditional or conditional status, unless granted exception status in accordance with § 405.2122(b);

(a) *Standard: Renal Transplantation Center.* (1) Unconditional status: 15 or more transplants performed annually.

(2) Conditional status: 7 to 14 transplants performed annually.

(b) *Standard: Dialysis facilities or centers performing greater than 20 percent of their dialyses on outpatients.*

(1) For any facility located within a standard metropolitan statistical area of 500,000 population or greater:

(i) Unconditional status—6 or more dialysis stations with performance of an average of 4.5 or more dialyses per station per week;

(ii) Conditional status—6 or more dialysis stations with performance of an average of between 4.0 and 4.5 dialyses per station per week; or 4 or 5 dialysis stations with performance of an average of 4.5 or more dialyses per station per week.

(2) For any facility located in a standard metropolitan statistical area of less than 500,000 population, or in an area not included in a standard metropolitan statistical area.

(i) Unconditional status—3 or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week;

(ii) Conditional status—2 dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

(c) *Standard: Renal dialysis centers performing 20 percent or less of their dialyses on outpatients:* (1) Unconditional status—3 or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week;

(2) Conditional status—2 dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

(d) Self-dialysis training stations which were utilized to successfully train at least six self-dialysis patients per station per calendar year and the dialyses performed on these stations may be excluded from the calculation of utilization rates.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48951, Oct. 19, 1978]

§ 405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center.

A renal transplantation center or a renal dialysis center (§ 405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

§ 405.2132 [Reserved]

§ 405.2133 Condition: Furnishing data and information for ESRD program administration.

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR Parts 5, 5b, and Part 401 of this chapter).

[53 FR 6548, Mar. 1, 1988]

§ 405.2134 Condition: Participation in network activities.

Each facility must participate in network activities and pursue network goals.

[51 FR 30362, Aug. 26, 1986]

§ 405.2135 Condition: Compliance with Federal, State and local laws and regulations.

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) *Standard: licensure.* Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

(1) Licensed pursuant to such law; or

(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) *Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law.

(c) *Standard: conformity with other laws.* The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

§ 405.2136 Condition: Governing body and management.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer who is responsible for the overall management of the facility.

(a) *Standard: disclosure of ownership.* The ESRD facility supplies full and complete information to the State survey agency (§ 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 per centum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility; (2) each officer and director of the corporation, if the facility is organized as a corporation; and (3) each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) *Standard: Operational objectives.* The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.

(3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see § 405.2137).

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(c) *Standard: chief executive officer.* The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities.

(3) The responsibilities of the chief executive officer include but are not limited to:

(i) Implementing the policies of the facility and coordinating the provision of services, in accordance with delegations by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) *Standard: personnel policies and procedures.* The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing inservice training, including procedures for infection control. Records are

maintained showing the content of training sessions and the attendance at such sessions.

(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.

(e) *Standard: use of outside resources.* If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) *Standard: patient care policies.* The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement).

(ii) Admission and discharge policies (in relation to both in-facility care and home care).

(iii) Medical supervision and physician services.

(iv) Patient long term programs, patient care plans and methods of implementation.

(v) Care of patients in medical and other emergencies.

(vi) Pharmaceutical services.

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).

(viii) Administrative records.

(ix) Use and maintenance of the physicial plant and equipment.

(x) Consultant qualifications, functions, and responsibilities.

(xi) The provision of home dialysis support services, if offered (see § 405.2163(e)).

(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physican director to (or, in the case of a self-dialysis unit, to another licensed health practitioner) a registered nurse, the physican-director provides medical guidance in such matters.

(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their nonworking hours.

(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see § 405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

(g) *Standard: medical supervision and emergency coverage.* The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers

indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) *Standard: medical staff.* The governing body of the ESRD facility designates a qualified physician (see § 405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§ 405.2137 Condition: Patient long-term program and patient care plan.

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) *Standard: patient long-term program.* There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see § 405.2161(b)(1) and § 405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see § 405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate. (See § 405.2163(e).)

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978]

§ 405.2138 Condition: Patients' rights and responsibilities.

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and Subpart Q of 20 CFR Part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) *Standard: informed patients.* All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) *Standard: participation in planning.* All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) *Standard: respect and dignity.* All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) *Standard: confidentiality.* All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) *Standard: grievance mechanism.* All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§ 405.2139 Condition: Medical records.

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record.* Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see § 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in § 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.

(b) *Standard: protection of medical record information.* The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) *Standard: medical records supervisor.* A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) *Standard: Completion of medical records and centralization of clinical information.* Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) *Standard: retention and preservation of records.* Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) *Standard: location and facilities.* The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) *Standard: transfer of medical information.* The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 52 FR 36934, Oct. 2, 1987]

§ 405.2140 Condition: Physical environment.

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) *Standard: building and equipment.* The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.

(4) [Reserved]

(5) Water used for dialysis purposes is analyzed periodically and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Records of test results and equipment maintenance are maintained at the facility.

(b) *Standard: favorable environment for patients.* The facility is maintained and equipped to provide a functional, sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items which conform to requirements for reuse in § 405.2150.

(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accomodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency. There is sufficient space in units for safe storage of self-dialysis supplies.

(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made.

(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.

(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see § 405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(c) *Standard contamination prevention.* The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures. The written patient care policies (see § 405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in § 405.2150.

(d) *Standard: emergency preparedness.* Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.

(Secs. 1102, 1871, 1881(b), Social Security Act; 42 U.S.C. 1302, 1395hh, 1395rr(b))

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 45 FR 24839, Apr. 10, 1980; 52 FR 36934, Oct. 2, 1987]

§ 405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section.

(a) *Standard: Hemodialyzers.* If the ESRD facility reuses hemodialyzers, it meets the voluntary guidelines adopted by the Association for the Advancement of Medical Instrumentation (A.A.M.I.) July 1986 (i.e., "Recommended Practice for Reuse of Hemodialyzers") which is incorporated by reference. Incorporation of the Association for the Advancement of Medical Instrumentation 1986 edition of the "Recommended Practice for Reuse of Hemodialyzers" was approved by the Director of the Federal Register in accordance with 5 U.S.C. 562(a) and 1 CFR Part 51 which governs the use of incorporations by reference.[1]

In addition to the A.A.M.I. 1986 edition criteria on hemodialyzer reuse, the ESRD facility conforms to the following procedures:

(1) *Chemical germicides.* To prevent any risk of dialyzer membrane leaks

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[1] The "Recommended Practice for Reuse of Hemodialyzers" is available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street NW., Washington, DC. Copies may be obtained from the Association for the Advancement of Medical Instrumentation, 1901 North Fort Myers Drive, Suite 602, Arlington, Va. 22209-1699.

If any changes in the "Recommended Practice for Reuse of Hemodialyzers" are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(2) *Staff exposure to chemical germicides.* Chemical germicides are handled in a manner to minimize exposure to staff members who are involved in the reprocessing. The following exposure limits for a number of active ingredients contained in formulations of chemical germicides utilized in dialysis facilities have been set by the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) (see 29 CFR 1910.1000). Staff exposure to any material in the table is consistent with these limits.

TABLE

Substance/material	Limits
Formaldehyde	3 ppm TWA. 5 ppm Ceiling. (1 ppm TWA proposed by OSHA).
Glutaraldehyde	None developed.
Phenol	5 ppm TWA.
Glutaraldehyde-Phenol	Individual standards of recommendations should apply.
Peracetic Acid	None developed.
Chlorine Dioxide Syn: Chlorine Oxide.	100 ppb TWA.
Hydrogen Peroxide	1 ppm TWA.
Chlorine	1 ppm Ceiling.

TWA = Time weighted average.
Ceiling = Maximum exposure ceiling.
ppm = Parts per million.
ppb = Parts per billion.

(3) *Surveillance of patient reactions.* In order to detect bacteremia, to maintain patient safety when unexplained events occur, and to provide the manufacturer with information so that prompt remedial action can be taken, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient;

(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated; and

(iii) Notifies the manufacturer, if these reactions appear to be associated with any commercially available germicide or a reprocessing device.

(b) *Standard: Dialyzer caps.* The ports of hemodialyzers may be capped with new or disinfected caps. If dialyzer blood port caps are reused, they are disinfected with the chemical germicide that is used for disinfecting the hemodialyzer or any other chemical germicide approved by the Environmental Protection Agency as a sterilant/sporicide.

(c) *Standard: Transducer filters.* To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

[52 FR 36935, Oct. 2, 1987]

§ 405.2160 Condition: Affiliation agreement or arrangement.

(a) A renal dialysis facility and a renal dialysis center (see § 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients' personal effects are assured.

§ 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See § 405.2102.)

(b) *Standard: On-duty personnel.* Whenever patients are undergoing dialysis: (1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care; (2) an adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and (3) an adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102.)

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services*—(1) *Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. Laboratory services are performed either by a Medicare-approved hospital or by a qualified Medicare-approved independent laboratory, except that hematocrit and clotting time, which the facility uses to monitor its patients' fluids incident to each dialysis treatment, may be performed by the dialysis facility's staff, who are qualified by education and experience to perform such duties, under the direction of a physician.

(c) *Standard: Social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) *Standard: Dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) *Standard: Self-dialysis support services.* The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A recordkeeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(f) *Standard: Participation in recipient registry.* The dialysis facility or center participates in a patient registry program with an OPO certified or recertified under Part 485, Subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 53 FR 6548, Mar. 1, 1988]

§ 405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§ 405.2130 through 405.2164, with the exception of §§ 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under § 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§ 405.2102) or a qualified physician-director (§ 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the Renal Transplantation Center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2171 Condition: Minimal service requirements for a renal transplant center.

Kidney transplantation is furnished directly by a hospital which is participating as a provider of services in the Medicare program and is approved by the Secretary as a Renal Transplantation Center. The Renal Transplantation Center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.

(a) *Standard: participation in recipient registry.* The Renal Transplantation Center participates in a patient registry program with an OPO certified or recertified under Part 485, Subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.

(b) *Standard: social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(c) *Standard: dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(d) *Standard: laboratory services.* The Renal Transplantation Center makes available, directly or under arrangements, laboratory services to met the needs of ESRD patients. Laboratory services are performed in a laboratory facility approved to participate in the Medicare program and, for histocompatibility testing purposes, notwithstanding approval pursuant to Subpart J also meets § 405.1314(b)(13) and § 405.1317(a), (b)(2) (i) and (ii), (b)(4), and (b)(8), and (when services are furnished in the specialty of tissue pathology) § 405.1314(b)(8)(i) and § 405.1317 (a) and (b)(6)(ii).

(1) Laboratory services for crossmatching of recipient serum and donor lymphocytes for preformed antibodies by an acceptable technique

are available on a 24-hour emergency basis.

(2) Available laboratory services also include:

(i) Suitable maintenance of recipient sera and typing reagents;

(ii) Phenotyping for donors and recipients;

(iii) Updating and retyping for HL-A and better defined antigens as indicated;

(iv) Screening of recipient sera for preformed antibodies with a suitable lymphocyte panel;

(v) Testing such as the mixed lymphocyte cultures to determine cellularly-defined antigens; and

(vi) ABO blood grouping and Rh typing.

(e) *Standard: Organ procurement.* A renal transplant center utilizing the services of an organ procurement organization certified or recertified under Part 485, Subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplant center agrees to notify the Secretary in writing within 30 days of the termination of such arrangements.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 30362, Aug. 26, 1986; 53 FR 6548, Mar. 1, 1988]

§ 405.2180 Termination of Medicare coverage.

(a) Except as provided in § 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this Subpart U will result in termination of Medicare coverage of the services furnished by that supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required by § 405.2134, coverage may be reinstated when HCFA determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until HCFA finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

[53 FR 36277, Sept. 19, 1988]

EFFECTIVE DATE NOTE: At 53 FR 36277, Sept. 19, 1988, § 405.2180 was added, effective October 19, 1988.

§ 405.2181 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* HCFA may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if HCFA finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that HCFA may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of sanction.* An alternative sanction remains in effect until HCFA finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

[53 FR 36277, Sept. 19, 1988]

EFFECTIVE DATE NOTE: At 53 FR 36277, Sept. 19, 1988, § 405.2181 was added, effective October 19, 1988.

§ 405.2182 Notice of sanction and appeal rights: Termination of coverage.

(a) *Notice of sanction.* HCFA gives the supplier and the general public notice of sanction and of the effective date of the sanction. The effective date of the sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under Part 498 of this chapter.

[53 FR 36277, Sept. 19, 1988]

EFFECTIVE DATE NOTE: At 53 FR 36277, Sept. 19, 1988, § 405.2182 was added, effective October 19, 1988.

§ 405.2184 Notice of appeal rights: Alternative sanctions.

If HCFA proposes to apply a sanction specified in § 405.2181(b), the following rules apply:

(a) HCFA gives the facility notice of the proposed sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, HCFA provides an informal hearing by a HCFA official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, HCFA provides the facility and the public, at least 30 days before the effective date of the sanction, with a written notice that specifies the effective date and the reasons for the sanction.

[53 FR 36277, Sept. 19, 1988]

EFFECTIVE DATE NOTE: At 53 FR 36277, Sept. 19, 1988, § 405.2180 was added, effective October 19, 1988.

Subpart X—Rural Health Clinic Services

AUTHORITY: Sec. 1102, 1833, 1861(aa), 1871, Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485; 42 U.S.C. 1302, 1395l, 1395hh, and 1395x(aa).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§ 405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

(1) "Act" means the Social Security Act.

(2) "Allowable costs" means costs that are incurred by a clinic and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic services.

(3) "Beneficiary" means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (Part B of title XVIII of the Act).

(4) "Coinsurance" means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

(5) "Carrier" means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

(6) "Covered services" means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

(7) "Deductible" means: (i) The first $75 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(ii) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See §§ 410.160 and 410.161 of this chapter for greater detail.)

(8) "HCFA" stands for Health Care Financing Administration.

(9) "Intermittent nursing care" means a medically predictable need for nursing care from time to time, but usually not less frequently than once every 60 days.

(10) "Nurse-midwife" means a registered professional nurse who meets the following requirements:

(i) Is currently licensed to practice in the State as a registered professional nurse.

(ii) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(iii) Except as provided in paragraph (b)(10)(iv) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(iv) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(A) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(B) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(C) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

(11) "Nurse practitioner" and "physician assistant" means individuals who meet the applicable education, training experience and other requirements of § 491.2 of this chapter.

(12) "Part-time nursing care" means nursing care that is required on less than a full-time basis, that is, less than 8 hours a day or 40 hours a week.

(13) "Physician" means: (i) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed; and

(ii) Within limitations as to the specific services furnished, a doctor of dentistry or dental or oral surgery, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor. (See section 1861(r) of the Act and § 405.232a of this part for specific limitations).

(14) "Reporting period" means a period of 12 consecutive months specified by the carrier as the period for which a clinic must report its costs and utilization. The first and last reporting periods may be less than 12 months.

(15) "Rural health clinic" means a facility that: (i) Has been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and Part 491 of this chapter; and

(ii) Has filed an agreement with the Secretary in order to provide rural health clinic services under Medicare. (See § 405.2402.)

(16) "Secretary" means the Secretary of Health and Human Services or his delegate.

(17) "Specialized nurse-practitioner" means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(i) Is currently certified as a nurse practitioner by the American Nurses' Association to perform specialized primary health care services; or

(ii) Has satisfactorily completed a formal educational program (of at least one academic year) that:

(A) Prepares registered nurses to perform an expanded role in the delivery of specialized primary health care services;

(B) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(C) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(iii) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in a delivery of specialized primary health care services) that does not meet the requirements of paragraph (b)(17)(ii) of this section, and has been performing an expanded role in the delivery of specialized primary health care services for a total of 12 months during the 18-month period immediately preceding the effective date of the regulations governing certification of rural health clinics (February 8, 1978).

(18) "Visit" means a face-to-face encounter between a clinic patient and a physician, physician assistant, nurse practitioner, nurse midwife, special-

ized nurse practitioner, or visiting nurse. Encounters with more than one health professional, and multiple encounters with the same health professional, which take place on the same day and at a single location constitute a single visit, except for cases in which the patient, subsequent to the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

(19) "Visiting nurse services" means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395*l*, 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986]

§ 405.2402 Basic requirements.

(a) *Certification by the State survey agency.* The rural health clinic must be certified in accordance with Part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish rural health clinic services.* If the Secretary, after reviewing the survey agency recommendation and other evidence relating to the qualifications of the rural health clinic, determines that it meets the requirements of this subpart and of Part 491 of this chapter, he will send the clinic:

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the rural health clinic.* If the rural health clinic wishes to participate in the program, it must:

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the rural health clinic, he will return to the clinic one copy of the agreement, with a notice of acceptance specifying the effective date.

(e) *Duration of agreement.* The agreement shall be for a term of one year and may be renewed annually by mutual consent of the Secretary and the rural health clinic.

(f) *Appeal rights.* If the Secretary does not certify a rural health clinic, or refuses to enter into or renew an agreement, the facility is entitled to a hearing in accordance with Part 498 of this chapter.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§ 405.2403 Content and terms of the agreement with the Secretary.

(a) Under the agreement, the rural health clinic agrees to the following:

(1) *Maintaining compliance with conditions.* The clinic agrees to maintain compliance with the conditions set forth in Part 491 of this chapter and to report promptly to HCFA any failure to do so.

(2) *Charges to beneficiaries.* The clinic agrees not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part (or for which the beneficiary would have been entitled if the rural health clinic had filed a request for payment in accordance with § 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under § 405.2410.

(3) *Refunds to beneficiaries.* (i) The clinic agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, "money incorrectly collected" means sums collected in excess of the amount for which the beneficiary was liable under § 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

(A) The beneficiary is later determined to have been entitled to Medicare benefits; and

(B) The beneficiary's entitlement period falls within the time the rural health clinic's agreement with the Secretary is in effect.

(4) *Beneficiary treatment.* (i) The clinic agrees to accept beneficiaries for care and treatment; and

(ii) The clinic agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) *Additional provisions.* The agreement may contain any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.2404 Terminations of agreements.

(a) *Termination by rural health clinic.* (1) *Notice to Secretary.* If the clinic wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) *Action by the Secretary.* (i) The Secretary may approve the date proposed by the clinic, or set a different date no later than 6 months after the date of the clinic's notice.

(ii) The Secretary may approve a date which is less than 6 months after the date of notice if he determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the clinic; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Cessation of business.* If a clinic ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the clinic, effective on the last day of business.

(b) *Termination by the Secretary.* (1) *Cause for termination.* The Secretary may terminate an agreement if he determines that the rural health clinic:

(i) No longer meets the conditions for certification under Part 491 of this chapter; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

(iii) Has undergone a change of ownership.

(2) *Notice of termination.* The Secretary will give notice of termination to the rural health clinic at least 15 days before the effective date stated in the notice.

(3) *Appeal by the rural health clinic.* A rural health clinic may appeal the termination of its agreement in accordance with the provisions set forth in Part 498 of this chapter.

(c) *Effect of termination.* Payment will not be available for rural health clinic services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination shall be given to the public, through publication in local newspapers:

(1) By the clinic, after the Secretary has approved or set a termination date; or

(2) By the Secretary, when he has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by the Secretary.* When an agreement with a rural health clinic is terminated by the Secretary, the rural health clinic may not file another agreement to participate in the Medicare program unless the Secretary:

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§ 405.2410 Beneficiary entitlement and liability.

(a) *Entitlement.* A beneficiary is entitled to have payment made on his or her behalf for rural health clinic services in accordance with this subpart.

(b) *Liability.* (1) The beneficiary's entitlement to payment begins only after the beneficiary has incurred the deductible;

(2) The beneficiary is responsible, in addition, for a coinsurance amount which cannot exceed 20 percent of the

clinic's reasonable customary charge for the covered service; and

(3) The beneficiary's deductible and coinsurance liability, with respect to any one item or service furnished by the clinic, may not exceed a reasonable amount customarily charged by the clinic for that particular item or service.

§ 405.2411 Scope of benefits.

(a) Rural health clinic services reimbursable under this subpart are:

(1) The physicians' services specified in § 405.2412;

(2) Services and supplies furnished as an incident to a physician's professional service;

(3) The nurse practitioner or physician assistant services specified in § 405.2414;

(4) Services and supplies furnished as an incident to a nurse practitioner's or physician assistant's services; and

(5) Visiting nurse services.

(b) Rural health clinic services are reimbursable when furnished to a patient at the clinic, at a hospital or other medical facility, or at the patient's place of residence.

§ 405.2412 Physicians' services.

(a) Physicians' services are professional services that are performed by a physician at the clinic or are performed away from the clinic by a physician whose agreement with the clinic provides that he or she will be paid by the clinic for such services.

§ 405.2413 Services and supplies incident to a physician's services.

(a) Services and supplies incident to a physician's professional service are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral, part of a physician's professional services;

(4) Furnished under the direct, personal supervision of a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§ 405.2414 Nurse practitioner and physician assistant services.

(a) Professional services are reimbursable under this subpart if:

(1) Furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner who is employed by, or receives compensation from, the rural health clinic;

(2) Furnished under the medical supervision of a physician;

(3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician;

(4) They are of a type which the nurse practitioner, physician assistant, nurse midwife or specialized nurse practitioner who furnished the service is legally permitted to perform by the State in which the service is rendered; and

(5) They would be covered if furnished by a physician.

(b) The physician supervision requirement is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of nurse practitioners, physician assistants, nurse midwives or specialized nurse practitioners are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

§ 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.

(a) Services and supplies incident to a nurse practitioner's or physician assistant's services are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practi-

tioner, physician assistant, nurse midwife, or specialized nurse practitioner;

(4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§ 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if:

(1) The rural health clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies;

(2) The services are rendered to a homebound individual;

(3) The services are furnished by a registered nurse, licensed practical nurse, or licensed vocational nurse who is employed by, or receives compensation for the services from the clinic; and

(4) The services are furnished under a written plan of treatment that is:

(i) Established and reviewed at least every 60 days by a supervising physician of the rural health clinic or established by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner and reviewed at least every 60 days by a supervising physician; and

(ii) Signed by the nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, or the supervising physician of the clinic.

(b) The nursing care covered by this section includes:

(1) Services that must be performed by a registered nurse, licensed practical nurse, or licensed vocational nurse if the safety of the patient is to be assured and the medically desired results achieved; and

(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, "homebound" means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, "place of residence" does not include a hospital or long term care facility.

§ 405.2417 Visiting nurse services: Determination of shortage of agencies.

A shortage of home health agencies exists if the Secretary determines that the rural health clinic:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the rural health clinic;

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency; or

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

§ 405.2418 Applicability of general payment exclusions.

The payment conditions, limitations, and exclusions set out in Subpart C of this part and Part 410 of this chapter are applicable to payment for services provided by rural health clinics.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.2425 Payment for rural health clinic services.

(a) *Payment to provider clinics.* A clinic will be paid in accordance with Subpart D of this part if:

(1) The clinic is an integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (i.e., a provider of services); and

(2) The clinic is operated with other departments of the provider under common licensure, governance and professional supervision.

(b) *Payment to independent clinics.* (1) All other clinics will be paid on the basis of an all inclusive rate for each beneficiary visit for covered services. This rate will be determined by the carrier, in accordance with this subpart and general instructions issued by HCFA.

(2) The amount payable by the carrier for a visit will be determined as follows:

(i) If the deductible has been fully incurred by the beneficiary prior to the visit, 80 percent of the all-inclusive rate will be paid.

(ii) If the deductible has not been fully incurred by the beneficiary before the visit, and the amount of the clinic's reasonable customary charges for the services that is applied to the deductible is less than the all-inclusive rate, the amount applied to the deductible will be subtracted from the all-inclusive rate and 80 percent of the remainder, if any, will be paid to the clinic.

(iii) If the deductible has not been fully incurred by the beneficiary before the visit, and the amount of the clinic's reasonable customary charges for the services that is applied to the deductible is equal to or exceeds the all-inclusive rate, no payment will be made to the clinic.

(3) In order to receive payment, the payment procedures established in accordance with § 410.165 of this chapter shall be followed.

[45 FR 13075, Feb. 28, 1980, as amended at 46 FR 41063, Aug. 14, 1981; 51 FR 41351, Nov. 14, 1986]

§ 405.2426 All-inclusive rate.

(a) *Determination of rate.* (1) An all-inclusive rate will be determined by the carrier at the beginning of the reporting period.

(2) The rate will be determined by dividing the estimated total allowable costs by estimated total visits for rural health clinic services.

(3) The rate determination will be subject to any tests of reasonableness that may be established in accordance with this subpart.

(b) *Adjustment of rate.* (1) The carrier will, during each reporting period, periodically review the rate to assure that payments approximate actual allowable costs and visits for rural health clinic services, and will adjust it if:

(i) There is a significant change in the utilization of clinic services;

(ii) Actual allowable costs vary materially from the clinic's estimated allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(2) The clinic may request the carrier to review the rate to determine whether adjustment is required.

§ 405.2427 Annual reconciliation.

(a) *General.* Payments made to a rural health clinic during a reporting period will be subject to reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation.* (1) The total reimbursement amount due the clinic for covered services furnished to Medicare beneficiaries will be based on the report specified in § 405.2429(c)(2) and will be calculated by the carrier as follows:

(i) The average cost per visit will be calculated by dividing the total allowable cost incurred for the reporting period by total visits for rural health clinic services furnished during the period. The average cost per visit will be subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of rural health clinic services furnished to Medicare beneficiaries will be calculated by multiplying the average cost per visit by the number of visits for covered rural health clinic services by beneficiaries.

(iii) The total reimbursement due the clinic will be 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries, that is attributable to rural health clinic services, from the cost of these services.

(2) The total reimbursement amount due shall be compared with total payments made to the clinic for the reporting period, and the difference shall constitute the amount of the reconciliation.

(c) *Notice of program reimbursement.* The carrier will send written notice to the clinic:

(1) Setting forth its determination of the total reimbursement amount due the clinic for the reporting period and the amount, if any, of the reconciliation; and

(2) Informing the clinic of its right to have the determination reviewed at a hearing under the procedures set forth in Subpart R of this part, if the amount in controversy is at least $1,000.

(d) *Payment of reconciliation amount*—(1) *Underpayments.* If the total reimbursement due the clinic exceeds the payments made for the reporting period, the carrier will make a lump-sum payment to the clinic to bring total payments into agreement with total reimbursement due the clinic.

(2) *Overpayments.* If the total payments made to a clinic for the reporting period exceed the total reimbursement due the clinic for the period, the carrier will arrange with the clinic for repayment through a lump-sum refund, or, if that poses a hardship for the clinic, through offset against subsequent payments or a combination of offset and partial refund. The repayment shall be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the carrier if the carrier is satisfied that unusual circumstances exist which warrant a longer period.

[43 FR 3261, Mar. 1, 1978, as amended at 46 FR 41063, Aug. 14, 1981]

§ 405.2428 Allowable costs.

(a) *Applicability of general Medicare principles.* In determining whether a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the principles for reimbursement of provider costs, as set forth in Subpart D of this part, will be followed as applicable.

(b) *Typical rural health clinic costs.* The following types and items of cost will be included in allowable costs to the extent that they are reasonable:

(1) Compensation for the services of physicians, physician assistants, nurse practitioners, nurse midwives, specialized nurse practitioners and visiting nurses employed by the clinic.

(2) Compensation for the duties that a supervising physician is required to perform under the agreement specified in § 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse midwife or specialized nurse practitioner.

(4) Overhead costs, including clinic adminstration, costs applicable to use and maintenance of the clinic facility, and depreciation costs.

(5) Costs of services purchased by the clinic.

(c) *Tests of reasonableness for rural health clinic cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by HCFA or the carrier with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. Those tests include, but are not limited to, screening guidelines and payment limitations.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines will not be included unless the clinic provides reasonable justification satisfactory to the carrier.

(2) Screening guidelines will be used to assess:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, nurse midwives and specialized nurse practitioners;

(ii) Physician, physician assistant, nurse practitioner, specialized nurse practitioner, nurse midwife, and visiting nurse productivity;

(iii) The level of admininstrative and general expenses;

(iv) Staffing (e.g., the ratio of other clinic personnel to physicians, physician assistants, and nurse practitioners); and

(v) The reasonableness of payments for services purchased by the clinic, subject to the limitation that the costs of physicians' services purchased by the clinic may not exceed the reasonable charges for these services as determined under Subpart E of this part.

(e) *Payment limitations.* Limits on payments may be set by HCFA, on the basis of costs estimated to be reasonable for the provision of such services.

§ 405.2429 Reports and maintenance of records.

(a) *Maintenance and availability of records.* The rural health clinic shall:

(1) Maintain adequate financial and statistical records, in the form and containing the data required by HCFA, to allow the carrier to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets will be allowable rather than the expenditure for the capital asset.

(b) *Adequacy of records.* (1) The carrier may suspend reimbursement if it determines that the clinic does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension will continue until the clinic demonstrates to the carrier's satisfaction that it does, and will continue to, maintain adequate records.

(c) *Reporting requirements*—(1) *Initial report.* At the beginning of its initial reporting period, the clinic shall submit an estimate of budgeted costs and visits for rural health clinic services for the reporting period, in the form and detail required by HCFA, and such other information as HCFA may require to establish the payment rate.

(2) *Annual reports.* Within 90 days after the end of its reporting period, the clinic shall submit, in such form and detail as may be required by HCFA, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for rural health clinic services furnished during the period; and

(ii) The estimated costs and visits for rural health clinic services for the succeeding reporting period, and such other information as HCFA may require to establish the payment rate.

(3) *Late reports.* If the clinic does not submit an adequate annual report on time, the carrier may reduce or suspend payments to preclude excess payment to the clinic.

(4) *Inadequate reports.* If the clinic does not furnish a report or furnishes a report that is inadequate for the carrier to make a determination of program payment, HCFA may deem all payments for the reporting period to be overpayments.

(5) *Postponement of due date.* For good cause shown by the clinic, the carrier may, with HCFA's approval, grant a 30-day postponement of the due date for the annual report.

(6) *Termination of agreement or change of ownership.* The report from a clinic which voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change in ownership is due no later than 45 days following the effective date of the termination of agreement or change of ownership.

§ 405.2430 Beneficiary appeals.

A beneficiary may request a hearing by a carrier (subject to the limitations and conditions set forth in Subpart H of this part) if:

(a) The beneficiary is dissatisfied with a carrier's determination denying a request for payment made on his or her behalf by a rural health clinic; or

(b) The beneficiary is dissatisfied with the amount of payment; or

(c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

Subpart A—Hospital Insurance Eligibility and Entitlement: General Provisions

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406.30 Nonpayment of benefits on behalf of certain aliens.
406.31 Conviction of subversive activities.

AUTHORITY: Secs. 202(t), 202(u), 226, 226A, 1102, 1818, and 1871 of the Social Security Act (42 U.S.C. 402(t) 402(u), 426, 426-1, 1302, 1395i-2, and 1395hh) and 3103 of Pub. L. 89-97 (42 U.S.C. 426a) unless otherwised noted.

SOURCE: 48 FR 12536, Mar. 25, 1983, unless otherwise noted. Redesignated at 51 FR 41338, Nov. 14, 1986.

Subpart A—Hospital Insurance Eligibility and Entitlement: General Provisions

§ 406.1 Statutory basis.

Sections 226, 226A, and 1818 of the Social Security Act and section 103 of Pub. L. 89-97 establish the conditions for entitlement to hospital insurance benefits. Sections 202 (t) and (u) of the Act specify limitations that apply to certain aliens and to persons convicted of certain offenses.

§ 406.2 Scope.

Subparts A through D of this part specify the conditions of eligibility for hospital insurance and set forth certain specific conditions that affect entitlement to benefits. Hospital insurance is authorized under Part A of Title XVIII and is also referred to as Medicare Part A. It includes inpatient hospital care, posthospital SNF care, home health services, and hospice care.

[48 FR 56026, Dec. 16, 1983, as amended at 50 FR 33033, Aug. 16, 1985. Redesignated and amended at 51 FR 41338, Nov. 14, 1986]

§ 406.3 Definitions.

"First month of eligibility" means the first month in which an individual meets all the requirements for entitlement to hospital insurance except application or enrollment if that is required.

"First month of entitlement" means the first month for which the individual meets all the requirements for entitlement to Part A benefits.

"Insured individual" means an individual who has the number of quarters of coverage required for monthly social security benefits.

"Quarter of coverage" means a calendar quarter that is counted toward the number of covered quarters required to make the individual eligible for monthly social security benefits. A quarter is counted if during that quarter (or that calendar year) the individual earned a required minimum amount of money. (For details, see 20 CFR Part 404, Subpart B.)

§ 406.5 Basis of eligibility and entitlement.

(a) *Hospital insurance without premiums.* Hospital insurance is available to most individuals without payment of a premium if they:

(1) Are age 65 or over, or

(2) Have received social security or railroad retirement disability benefits for 25 months; or

(3) Have end-stage renal disease. Subpart B of this part explains the requirements such individuals must meet to obtain hospital insurance without premiums.

(b) *Premium hospital insurance.* Many individuals who are age 65 or over, but do not meet the requirements set forth in Subpart B of this part, may obtain the benefits by paying a premium. Section 406.20 of this part explains the requirements individuals must meet to obtain premium hospital insurance.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 406.6 Application or enrollment for hospital insurance.

(a) *Basic provision.* In most cases, eligibility for Medicare Part A is a result of entitlement to monthly social security or railroad retirement cash benefits or eligibility for monthly social security cash benefits. This section specifies the individuals who need not file an application to become entitled to hospital insurance, those who must file an application, and those who must enroll.

(b) *Individuals who need not file an application for hospital insurance.* An individual who is already entitled to monthly social security or railroad retirement benefits when he or she attains age 65 or who establishes entitlement to those benefits after age 65 need not file a separate application to become entitled to hospital insurance. (See 20 CFR Part 404, Subpart D for eligibility requirements for social security cash benefits, and Subpart G for requirements for filing applications for cash benefits.)

(c) *Individuals who must file an application for hospital insurance.* An individual must file an application for hospital insurance if he or she seeks entitlement to hospital insurance on the basis of—

(1) The transitional provisions set forth in § 406.11;

(2) Deemed entitlement to disabled widow's or widower's benefit under certain circumstances as provided in § 406.12;

(3) A diagnosis of end-stage renal disease, as specified in § 406.13; or

(4) Effective January 1, 1981, eligibility for social security cash benefits, as specified in § 406.10(a)(3), if the individual has attained age 65 without applying for those benefits.

(d) *When application is deemed to be filed.* (1) An application based on the transitional provisions or on ESRD is deemed to be filed in the first month of eligibility if it is filed not more than 3 months before the first month, and is retroactive to that month if filed within 12 months after the first month. An application filed more than 12 months after the first month of eligibility is retroactive to the 12th month before the month it is filed.

(2) An application for deemed entitlement to disabled widow's or widower's benefits, that is filed before the first month in which the individual meets all conditions of entitlement for this benefit, will be deemed a valid application if those conditions are met before an initial determination, reconsideration, or hearing decision is made on the application. If the conditions are met after the date of any hearing decision, a new application will have to be filed. An application validly filed within 12 months after the first month of eligibility is retroactive to that first month. If filed more than 12 months after that first month, it is retroactive to the 12th month before the month of filing.

(3) Effective June 8, 1980, an application based on eligibility for social security benefits at or after age 65, that is filed before the first month in which the individual meets all eligibility conditions for this benefit, will be deemed a valid application if those conditions are met before an initial determination, reconsideration, or hearing decision is made on the application. If the conditions are met after the date of any hearing decision, a new application will have to be filed.

(4) Effective March 1, 1981, an application under § 406.10 that is validly filed within 6 months after the first month of eligibility is retroactive to that first month. If filed more than 6 months after that first month, it is retroactive to the 6th month before the month of filing.

(e) *Individuals who must enroll for hospital insurance.* An individual who must pay a monthly premium for hospital insurance must enroll in accordance with the procedures set forth in § 406.21.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 406.7 Forms to apply for entitlement under Medicare Part A.

The following forms, available free of charge by mail from HCFA or at any Social Security branch or district office, are used to apply for Medicare entitlement under the circumstances indicated:

HCFA-18-F-5—Application for Hospital Insurance Entitlement. (For use by individuals who are not eligible for retirement benefits under Title II of the Social Security Act or under the Railroad Retirement Act. This form may also be used for enrollment in the supplementary medical insurance program.)

HCFA-43—Application for Health Insurance Benefits under Medicare for Individuals with End Stage Renal Disease (ESRD). (An initial application for entitlement by individuals with ESRD).

As an alternative, an individual may use the application for monthly social benefits to apply also for Medicare entitlement if he or she is eligible for hospital insurance at that time.

[53 FR 6633, Mar. 2, 1988]

Subpart B—Hospital Insurance Without Premiums

§ 406.10 Individual age 65 or over who is entitled to social security or railroad retirement benefits, or who is eligible for social security benefits.

(a) *Requirements.* An individual is entitled to hospital insurance benefits under section 226 of the Act if he or she has attained aged 65 and is:

(1) Entitled to monthly social security benefits under section 202 of the Social Security Act;

(2) A qualified railroad retirement beneficiary who has been certified as such to the Social Security Administration by the Railroad Retirement Board in accordance with section 7(d) of the Railroad Retirement Act of 1974; or

(3) Effective January 1, 1981, eligible for monthly social security benefits under section 202 of the Act and has filed an application for hospital insurance.

(b) *Beginning and end of entitlement.* (1) Entitlement begins with the first day of the first month in which the individual meets the requirements of paragraph (a) of this section.

(2) Entitlement continues until the individual dies or no longer meets the requirements of paragraph (a) of this section. An individual is not entitled to railroad retirement benefits and is neither entitled to, nor eligible for, monthly social security benefits in the month in which he or she dies. However, an individual who meets all other requirements for hospital insurance entitlement is entitled to hospital insurance in the month in which he or she dies if he or she—

(i) Would have been entitled to monthly railroad retirement benefits or social security benefits in that month if he or she had not died; or

(ii) Has filed an application for hospital insurance and would have been eligible for monthly social security benefits in that month if he or she had not died.

§ 406.11 Individual age 65 or over who is not eligible for social security or railroad retirement benefits.

(a) *Basis.* Section 103 of the law that established the Medicare program in 1965 (Pub. L. 89-97) provided for eligibility for certain individuals who were age 65 or would soon attain age 65 but would not be able to qualify for social security or railroad retirement benefits.

(b) *Requirements.* Unless he or she is excluded under paragraph (c) of this section, an individual age 65 or over who does not meet the requirements of § 406.10 (and who would not meet those requirements if he or she filed an application), is entitled to Medicare Part A benefits if he or she meets the following requirements:

(1) *Age and quarters of coverage.* (i) He or she attained age 65 before 1968; or

(ii) If he or she attained age 65 in 1966 or later, he or she must have at least 3 quarters of coverage for each year that elapsed after 1968 and before the year in which he or she attained age 65. (The quarters of coverage may have been acquired at any time, not necessarily during the elapsed years.)

(2) *Residence and citizenship.* He or she is a resident of the United States and—

(i) A citizen of the United States; or

(ii) An alien lawfully admitted for permanent residence who has continuously resided in the United States for 5 years immediately preceding the first month in which he or she meets all other requirements for entitlement to hospital insurance.

(3) *Application.* He or she has filed an application for Medicare Part A no earlier than the third month before the first month of eligibility.

(c) *Bases for exclusion.* An individual who meets the requirements of paragraph (b) of this section is excluded from Medicare Part A if he or she—

(1) Has been convicted of spying, sabotage, or treason, sedition, and subversive action under chapter 37, 105, or 115 of title 18 of the United States Code;

(2) Has been convicted of conspiracy to establish a dictatorship under section 4 of the Internal Security Act of 1950;

(3) On February 16, 1965, was or could have been covered under the Federal Employees Health Benefits Act (FEHBA) of 1959; or

(4) In his or her first month of eligibility;

(i) Is covered by an enrollment under the FEHBA; or

(ii) Could have been covered by an enrollment under that Act if he or she (or any other person who could provide him or her with coverage) was a Federal employee at any time after February 15, 1965, and had enrolled and retained coverage under that Act.

(d) *End of exclusion.* An individual excluded under paragraph (c)(3) or (4) of this section can become entitled beginning with the first month in which he or she loses the right to FEHBA coverage solely because he or she or the other person leaves Federal employment.

(e) *Beginning and end of entitlement.* (1) Entitlement begins—

(i) In the first month of eligibility if the application is filed no later than 12 months after the first month of eligibility:

(ii) In the 12th month before the month of application if the application is filed more than 12 months after the first month of eligibility.

(2) Entitlement continues until death or until the month before the month in which the individual becomes entitled under § 406.10.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 406.12 Individual under age 65, who is entitled to social security or railroad retirement disability benefits.

(a) *Basic requirements.* An individual under age 65 is entitled to hospital insurance benefits if, for 25 months, he or she has been—

(1) Entitled or deemed entitled to social security disability benefits as an insured individual, child, widow, or widower who is "under a disability" or

(2) A disabled qualified beneficiary certified under Section 7(d) of the Railroad Retirement Act.

(b) *Previous periods of disability benefit entitlement.*[1] Months of a previous period of entitlement or deemed entitlement to disability benefits will count toward the 25-month requirement if—

(1) Entitlement was as an insured individual or a disabled qualified railroad retirement beneficiary, and the previous period ended within the 60

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[1] Before December 1, 1980, the law required that the 25 months of disability entitlement be consecutive. The Social Security Disability Amendments of 1980 deleted that requirement.

months preceding the month in which the current disability began; or

(2) Entitlement was as a disabled child, widow, or widower, and the previous period ended within the 84 months preceding the month in which the current disability began.

(c) *Deemed entitlement to disabled widow's or widower's monthly benefits*—(1) *Purpose.* The provisions of paragraphs (c) (2), (3), and (4) of this section are intended to enable individuals—

(i) To meet the 25-month requirement of paragraph (a) of this section; or

(ii) To retain hospital insurance entitlement when they are no longer entitled to monthly disability benefits.

(2) *Deemed entitlement for certain individuals entitled to old-age insurance benefits.* An individual who becomes entitled to monthly old-age insurance benefits before age 65, is, by law, precluded from establishing or retaining entitlement to disabled widow's or widower's monthly benefits. However, for purposes of meeting the 25-month requirement, a widow or widower who meets all other requirements for disability benefits and is excluded solely because of entitlement to old-age insurance benefits, shall be deemed to be (or to continue to be) entitled to disability benefits. A widow or widower who is not entitled to disability benefits for the month before attaining age 60 must file two applications, one for old-age insurance benefits and one for hospital insurance.

(3) *Deemed entitlement for certain individuals entitled to mother's benefits.* An individual entitled to mother's insurance benefits under section 202(g) of the Social Security Act cannot at the same time be entitled to disabled widow's benefits. However, if she applies for hospital insurance, she will be deemed to be entitled to disabled widow's monthly benefits in the first month (of the 12 months before application) in which she would have been entitled to those benefits if she had filed an application for them.

(4) *Deemed retroactive entitlement for certain disabled widows and widowers.* In some cases, disabled widows or widowers cannot become entitled to monthly cash benefits before the month in which they file application. However, for purposes of meeting the 25-month requirement, disability benefit entitlement will be deemed to have begun with the earliest month (of the 12 months before the application for cash benefits) in which the individual met all the requirements except the filing of an application. (This provision is effective for applications filed on or after January 1, 1978.)

(d) *When entitlement begins and ends.* (1) Entitlement to hospital insurance begins with the 25th month of an individual's entitlement or deemed entitlement to disability benefits. Although an individual is not entitled to disability benefits for the month in which he or she dies, for purposes of this paragraph the individual will be deemed to be entitled for the month of death.

(2) Except as provided in paragraph (e) of this section, entitlement to hospital insurance ends with the earliest of the following:

(i) The last day of the last month in which he or she was entitled or deemed entitled to disability benefits or was qualified as a disabled railroad retirement beneficiary, if he or she was notified of the termination of entitlement before that month.

(ii) The last day of the month following the month in which he or she is mailed a notice that his or her entitlement or deemed entitlement to disability benefits, or his or her status as a qualified disabled railroad retirement beneficiary, has ended.

(iii) The last day of the month before the month he or she attains age 65. (An individual who is entitled to social security or railroad retirement cash benefits for the month of attainment of age 65 is automatically entitled to hospital insurance under § 406.10.)

(iv) The day of death.

(e) *Continuation of Medicare entitlement when disability benefit entitlement ends because of substantial gainful activity*—(1) *Definition.* As used in this paragraph (e), *"trial work period"* means the 9-month period provided under title II of the Act, during which the individual may test his or her ability to work and still receive disability cash benefits.

(2) *Duration of continued Medicare entitlement.* Effective December 1, 1980, if an individual's entitlement to disability benefits or status as a qualified disabled railroad retirement beneficiary ends because he or she engaged in, or demonstrated the ability to engage in, substantial gainful activity after the 15 months following the end of the trial work period, Medicare entitlement continues until the earlier of the following:

(i) The last day of the 24th month after the month in which the individual's entitlement to disability benefits or status as a qualified railroad retirement beneficiary ends if—

(A) The physical or mental impairment, on which that entitlement or status was based, continues through the 24-month period; and

(B) The individual remains otherwise eligible for disability benefits throughout this period.

(ii) The last day of the month following the month in which notice is mailed to the individual indicating that he or she is no longer entitled to hospital insurance because of an event or circumstance (e.g., the impairment has ceased, or the disabled widow has remarried) that would terminate disability benefit entitlement if it had not already been terminated because of substantial gainful activity.

§ 406.13 Individual who has end-stage renal disease.

(a) *Statutory basis and applicability.* This section explains the conditions of entitlement to hospital insurance benefits on the basis of end-stage renal disease, and specifies the beginning and end of the period of entitlement. It implements section 226A of the Social Security Act.

(b) *Definitions.* As used in this section:

"End-stage renal disease" (ESRD) means that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

"Child" or *"spouse"* means a child or spouse whose relationship to the parent or spouse meets the relationship requirements for entitlement to child's monthly social security benefits or to wife's, husband's, widow's, widower's, mother's or father's monthly benefits, as set forth in 20 CFR Part 404. However, the duration of relationship requirements apply only to divorced spouses. (See 20 CFR 404.331.)

"Dependent child" means a person who, on the first day he or she has end-stage renal disease, is unmarried and meets the dependency requirements for entitlement to child's social security benefits on the basis of a parent's earnings (see 20 CFR 404.350-404.365) and who—

(1) Is under age 22;

(2) Is under a disability that began before age 22; or

(3) Is under age 26, is receiving at least one-half support from that parent, and has continuously received at least one-half support from that parent since the day before attaining age 22.

"One-half support" means regular contributions, in cash or in kind, that equals or exceeds one-half of the child's total support.

(c) *Requirements.* An individual is entitled to hospital insurance benefits if—

(1) He or she is medically determined to have ESRD;

(2) He or she is:

(i) Fully or currently insured under the social security program (title II of the Act) or would be fully or currently insured if his or her employment (after 1936) as defined under the Railroad Retirement Act were considered "employment" under the Social Security Act;

(ii) Entitled to monthly social security or railroad retirement benefits; or

(iii) The spouse or dependent child of a person who meets the requirements of paragraph (c)(2)(i) or (c)(2)(ii) of this section;

(3) He or she has filed an application for Medicare Part A; and

(4) He or she has satisfied the waiting period explained in paragraph (e) of this section.

(d) *Filing an application.* (1) An individual may obtain an application form, and help in completing it, from any social security office.

(2) An application is not valid if it is filed earlier than the third month before the month in which the individ-

ual meets the conditions of paragraphs (c)(1), (c)(2), and (c)(4) of this section.

(3) If an individual who has ESRD dies before he or she has filed an application, or is unable to file because of physical or mental condition, a relative or other person responsible for his or her affairs may file in his or her behalf. If a responsible person is not available, the hospital or dialysis facility that furnished treatment may file the application.

(e) *Beginning of entitlement*—(1) *Basic limitations.* Entitlement can begin no earlier than the first month in which the individual meets the conditions specified in paragraph (c) of this section, or the 12th month before the month of application, whichever is later.

(2) *Waiting period.* Entitlement begins on the first day of the third month after the month in which the individual initiates a regular course of renal dialysis, if the course is maintained throughout the waiting period, unless entitlement would begin earlier under paragraph (e) (3) or (4) of this section. This means that if dialysis began in January, entitlement would begin April 1.

(3) *Exceptions: Early kidney transplant.* If the individual receives a transplant, entitlement begins with the first day of the month in which the transplant was performed. However, if the individual is admitted as an inpatient to a hospital that is an approved renal transplantation center or renal dialysis center (see § 405.2102) for procedures preliminary to transplant surgery, entitlement begins—

(i) On the first day of the month in which he or she initially enters the hospital, if the transplant is performed in that month or in either of the next 2 months; or

(ii) On the first day of the second month before the month of kidney transplantation, if the transplant is delayed more than 2 months after the month of initial hospital stay.

For example, if an individual enters the hospital in January, and the transplant is performed in January, February, or March, entitlement would begin January 1. However, if the transplant is performed in April, entitlement would begin February 1.

(4) *Exceptions: Self-dialysis training.* Entitlement begins on the first day of the month in which a regular course of renal dialysis began if:

(i) Before the end of the waiting period, the individual participates in a self-dialysis training program offered by a participating Medicare facility that is approved to provide such training;

(ii) The patient's physician has certified that it is reasonable to expect the individual will complete the training program and will self-dialyze on a regular basis; and

(iii) The regular course of dialysis is maintained throughout the time that would otherwise be the waiting period (unless it is terminated earlier because the individual dies).

(f) *End of entitlement.* Entitlement ends with:

(1) The end of the 12th month after the month in which a course of dialysis ends, unless the individual receives a kidney transplant during that period or begins another regular course of dialysis; or

(2) The end of the 36th month after the month in which the individual has received a kidney transplant, unless the individual receives another kidney transplant or begins a regular course of dialysis during that period.

(g) *Resumption of entitlement.* An individual who initiates dialysis more than 36 months after the month of a kidney transplant or resumes dialysis more than 12 months after the month a previous course of dialysis ended must submit a new application but need not serve a waiting period. If he or she is otherwise entitled under the conditions specified in paragraph (c) of this section, and files an application, entitlement begins with the month in which dialysis is initiated or resumed, subject to the limitations of paragraph (e)(1) of this section.

Subpart C—Premium Hospital Insurance

§ 406.20 Basic requirements.

(a) *General provisions.* Hospital insurance benefits are available to most individuals age 65 or over who do not qualify for those benefits under Subpart B of this part and are willing to pay a monthly premium. This is called premium hospital insurance.

(b) *Eligibility to enroll for premium hospital insurance.* An individual is eligible to enroll for Medicare Part A if he or she.

(1) Has attained age 65;

(2) Is a resident of the United States and is either—

(i) A citizen of the United States; or

(ii) An alien lawfully admitted for permanent residence who has resided in the United States continuously for the 5-year period immediately preceding the month in which he or she meets all other requirements;

(3) Is not eligible for Part A benefits under Subpart B of this part; and

(4) Is entitled to supplementary medical insurance (Part B of Medicare) or is eligible and has enrolled for it during an enrollment period.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 406.21 Enrollment and entitlement.

(a) *Basic provision.* An individual who meets the requirements of § 406.20(b) may enroll for premium hospital insurance only during his or her "initial enrollment period" or a "general enrollment period," as set forth in paragraphs (b) through (d) of this section.

(b) *Initial enrollment period.* (1) *Duration.* The initial enrollment period extends for 7 months, from the third month before the month the individual first meets the requirements of § 406.20 (b)(1) through (b)(3) through the third month after that first month of eligibility.

(2) *Effect of month of enrollment on entitlement.* (i) If the individual enrolls during the 3 months before the first month of eligibility, entitlement begins with the first month of eligibility.

(ii) If the individual enrolls in the first month of eligibility, entitlement begins with the following month.

(iii) If the individual enrolls during the month after the first month of eligibility, entitlement begins with the second month after the month of enrollment.

(iv) If the individual enrolls in either of the last 2 months of the enrollment period, entitlement begins with the third month after the month of enrollment.

(c) *General enrollment period.* (1) Except as specified in paragraph (c)(4) of this section, the general enrollment period extends from January 1 to March 31 of each calendar year.

(2) General enrollment periods are for individuals who fail to enroll during their initial enrollment periods or whose previous periods of entitlement has terminated.

(3) If the individual enrolls or reenrolls during a general enrollment period, his or her entitlement begins on July 1 of the calendar year.

(4) During the period April 1 through September 30, 1981, the general enrollment period was any time after the end of the individual's initial enrollment period. Any eligible individual whose initial enrollment period has ended, or whose previous period of entitlement had terminated, could enroll or reenroll during that 6-month period.

(d) *"Deemed" initial enrollment period.* (1) If an individual fails to enroll during the initial enrollment period because of reliance on incorrect documentary information which led him or her to believe that he or she was not yet age 65, an initial enrollment period may be established for him or her as though he or she had attained age 65 on the date indicated by the incorrect documentary information.

(2) The deemed initial enrollment period will be used to determine the individual's premium and right to enroll in a general enrollment period if such use is advantageous to the individual.

§ 406.22 Monthly premiums.

(a) *General provisions.* (1) For months before July 1974, the monthly premium was $33.

(2) For months after June 1974, premiums have been determined for each 12-month period beginning July 1, and published in the FEDERAL REGISTER during the last quarter of the preceding calendar year.

(b) *Monthly premiums: Determination of dollar amount.* (1) The dollar amount is determined by multiplying $33 by the ratio of next year's inpatient deductible to $76, which was the inpatient deductible determined for 1973. (Because of cost controls, the deductible actually charged for that year was $72.)

(2) The amount determined by the mathematical formula is rounded to the nearest multiple of $1. (Fifty cents is rounded to the next higher dollar.)

(c) *Monthly premiums. Increase for late enrollment and for reenrollment.* For an individual who enrolls after the close of the initial enrollment period or reenrolls, the amount of the monthly premium, as determined under paragraph (b) of this section, is increased by 10% for each full 12 months in the periods described in §§ 406.23 and 406.24.

(d) *Collection of monthly premiums.* (1) HCFA will bill the enrollee on a monthly basis and include an addressed return envelope with the bill.

(2) The enrollee must pay by check or money order that is payable to "HCFA Medicare Insurance," and shows his or her name and the claim number that appears on his or her Medicare card. He or she must return the bill with the check or money order.

§ 406.23 Determination of months to be counted for premium increase: Enrollment.

(a) *Enrollment before April 1, 1981 or after September 30, 1981.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the end of the general enrollment period in which the individual enrolls, excluding any months before September 1973.

(b) *Enrollment during the period April 1 through September 30, 1981.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the month in which the individual enrolled, excluding any months before September 1973.

(c) *Examples.* (1) John F's initial enrollment period ended July 1979 but he did not enroll until January 1980. The months to be counted are August 1979 through March 1980. Since only 8 months elapsed, there is no premium increase.

(2) Mary T's initial enrollment period ended in April 1980 but she did not enroll until May 1981. The months to be counted are May 1980 through May 1981. Since 13 months has elapsed, the premium would be increased by 10 percent.

§ 406.24 Determination of months to be counted for premium increase: Reenrollment.

(a) *First reenrollment before April 1, 1981 or after September 30, 1981.* The months to be counted for premium increase are:

(1) The months specified in § 406.23(a) or (b); plus

(2) The months from the end of the first period of entitlement through the end of the general enrollment period in which the individual reenrolled.

(b) *First reenrollment during the period April 1, 1981* through September 30, 1981. The months to be counted for premium increase are—

(1) The months specified in § 406.23(a); plus

(2) The months from the end of the first period of entitlement through the month in which the individual reenrolled.

(c) *Subsequent reenrollment during the period April 1, 1981 through September 30, 1981.* The months to be counted for premium increase are—

(1) The months specified in paragraph (a) of this section; plus

(2) The months from April 1981 through the month in which the individual reenrolled for the second time. (Since only one reenrollment was permitted before April 1981, any months from the end of the individual's first enrollment period of entitlement through March 1981 are not counted.)

(d) *Subsequent reenrollment after September 30, 1981.* The months to be counted for premium increase are—

(1) The months specified in paragraph (a) or (b) of this section, for the first and second periods of coverage; plus

(2) The months from the end of each subsequent period of entitlement through the end of the general enrollment period in which the individual reenrolled, excluding any months before April 1981.

(e) *Example.* Peter M enrolled during his initial enrollment period, terminated his first coverage period in August 1979 and reenrolled for the first time in January 1980. The 7 months to be counted (September 1979 through March, 1980) were not enough to require any increase in the premium. Peter terminated his second period of coverage in February 1981 and reenrolled for the second time in July 1981. Since the 4 months (April through July 1981), when added to the previous 7 months, bring the total to only 11 months, no premium increase is required.

§ 406.25 Termination of entitlement.

Any of the following actions or events will terminate entitlement:

(a) *Filing of request for termination.* The beneficiary may at any time give HCFA or the Social Security Administration written notice that he or she no longer wishes to participate in the premium hospital insurance program.

(1) If he or she files the notice before entitlement begins, he or she will be deemed not to have enrolled.

(2) If he or she files the notice after entitlement begins, that entitlement will end at the close of the month following the month in which he or she filed the notice.

(b) *Eligibility for hospital insurance without premiums.* (1) If an individual meets the eligibility requirements for hospital insurance specified in § 406.10 or § 406.11, entitlement to premium hospital insurance ends with the month before the month in which he or she meets those requirements.

(2) If an individual meets the requirements of § 406.10 or § 406.11, he or she will be deemed to have filed the required application for hospital insurance benefits in his or her first month of eligibility under that section.

(c) *Termination of supplementary medical insurance.* If an individual's entitlement to supplementary medical insurance ends for any reason, entitlement to premium hospital insurance will end on the same date.

(d) *Nonpayment of premium.* (1) If an individual fails to pay the premium bill, entitlement will end on the last day of the third month after the billing month.

(2) HCFA may reinstate entitlement if the individual shows good cause for failure to pay on time, and pays all overdue premiums within 3 calendar months after the date specified in paragraph (d)(1) of this section.

(e) *Death.* Entitlement ends with the day of death. (A premium is due for the month of death.)

§ 406.26 Prejudice to enrollment rights because of Federal Government error.

(a) If an individual's enrollment or nonenrollment for premium hospital insurance is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal Government to act on its behalf, the Social Security Administration or HCFA may take whatever action it determines is necessary to provide appropriate relief.

(b) The action may include—

(1) Designation of a special initial or general enrollment period;

(2) Designation of an entitlement period;

(3) Adjustment of premiums;

(4) Any combination of the actions specified in paragraph (b) (1) through (3) of this section; or

(5) Any other remedial action which may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction.

Subpart D—Special Circumstances that Affect Entitlement to Hospital Insurance

§ 406.30 Nonpayment of benefits on behalf of certain aliens.

(a) Hospital insurance benefit payments may not be made for services furnished to an alien in any month in which his or her monthly social security benefits are suspended (or would be suspended if he or she were entitled to those benefits) because the alien remains outside the United States for more than 6 months.

(b) Benefits will be payable beginning with services furnished in the first full calendar month the alien is back in the United States.

§ 406.31 Conviction of certain offenses.

(a) *Penalty that affects entitlement.* (1) If an individual is convicted of any of the crimes listed in § 406.11(c) (1) and (2), the court may impose, in addition to all other penalties, a penalty that affects entitlement to hospital insurance, beginning with the month of conviction.

(2) The additional penalty is that the individual's income (or the income of the insured individual on whose earnings record he or she became or seeks to become entitled) for the year of conviction and any previous year may not be counted in determining the insured status necessary for entitlement to hospital insurance.

(b) *Effect of pardon.* If the President of the United States pardons the convicted individual, that individual regains (or may again seek) entitlement effective with the month following the month in which the pardon is granted.

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408.112 Refund of excess premiums after the enrollee dies.

AUTHORITY: Secs. 1102, 1818, 1837—1840, 1843, 1871 and 1881(d) of the Social Security Act (42 U.S.C. 1302, 1395l-2, 1395p—1395s, 1395v, 1395hh, and 1395rr(d)), and the Federal Claims Collection Act (31 U.S.C. 3711).

SOURCE: 52 FR 48115, Dec. 18, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 408.1 Statutory basis.

(a) This part implements certain provisions of sections 1837 through 1840 and 1881(d) of the Social Security Act (the Act) and conforms to other regulations that implement section 1843 of the Act. Section 1838(b) requires regulations to establish when an individual's coverage ends because of nonpayment of premiums. It also specifies that those regulations may provide a grace period for payment of overdue premiums without loss of coverage. Section 1839 sets forth the specific procedures for determining the amount of the monthly premium and section 1840 establishes the rules for payment of premiums. Section 1843 provides that a State may enter into a buy-in agreement to secure SMI coverage for certain individuals by enrolling them in the SMI program and paying the premiums on their behalf. Section 1881(d) provides that Medicare payment, for the reasonable charges incurred in connection with a kidney donation, shall be made (without regard to deductible, premium, or coinsurance provisions of title XVIII) as prescribed in regulations.

(b) The Federal Claims Collection Act (31 U.S.C. 3711), as implemented by 4 CFR Parts 101-105, provides the basic authority for recovery of debts owed the United States government and specifies the conditions for the suspension or termination of collection action. Departmental regulations at 45 CFR Part 430, updated by a final rule published on January 5, 1987 (52 FR 260) set forth procedures for the exercise of the Department's authority to collect and dispose of debts and were intended to complement rules applicable to particular programs. HCFA rules are set forth at 42 CFR Part 401, Subpart F.

[52 FR 48115, Dec. 18, 1987; 53 FR 4158, Feb. 12, 1988]

§ 408.2 Scope and purpose.

(a) This part sets forth the policies and procedures for determining the amount of monthly supplementary medical insurance (SMI) premiums, for the payment, collection, or refund of premiums, for termination of coverage because of nonpayment of premiums, and for reinstatement of coverage if certain conditions are met. It conforms to Subpart B of Part 405 of this chapter, which sets forth the requirements for State buy-in agreements. These policies are intended to protect enrollee coverage to the maximum degree compatible with maintaining the integrity of the SMI program.

(b) Policies that apply to premiums that certain individuals must pay in order to become entitled to Medicare Part A hospital insurance benefits, are set forth in Part 406 of this chapter.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.3 Definitions.

As used in this part, unless the context indicates otherwise—

Enrollee means an individual who is enrolled in the SMI program under Medicare Part B.

Taxable year means the 12-month period (calendar or fiscal year) for which the individual files his or her income tax return.

§ 408.4 Payment obligations.

(a) *Month for which payment is due.* (1) A payment is due for each month, beginning with the first month of SMI coverage and continuing through the month of death or, if earlier, the month in which coverage terminates.

(2) A premium is due for the month of death, if SMI coverage is still in effect, even though the individual dies on the first day of the month.

(b) *Overdue premiums.* (1) Overdue premiums constitute an obligation enforceable against the enrollee or the enrollee's estate.

(2) Overdue premiums are collected—

(i) By deduction from social security or railroad retirement benefits or Federal civil service annuities;

(ii) Directly from the enrollee or the enrollee's estate; or

(iii) By offset against any SMI payments payable to the enrollee or the enrollee's estate.

(3) Interest is not charged on overdue premiums, except under a State buy-in agreement, as provided in § 408.6(c)(4).

(c) *Premiums not required for certain kidney donors.* (1) No premiums are required for SMI benefits related to the donation of a kidney if the donor is not an enrollee.

(2) A kidney donor who is an enrollee is not relieved of the obligation for premiums.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.6 Methods and priorities for payment.

(a) *Methods of payment*—(1) *General rules.* Premiums are paid by one of the following four methods:

(i) Payment by a State under a buy-in agreement.

(ii) Deduction from monthly railroad retirement of social security cash benefits or Federal civil service annuities.

(iii) Direct remittance on an individual basis, by or on behalf of the enrollee.

(iv) Direct remittance on a group basis, by an employer, union, lodge or other organization, or by an entity of State or local government.

(2) *Special situations.* (i) If the monthly social security benefit or age 72 special benefit is less than the monthly premium, the benefit is withheld and the enrollee is required to pay the balance through direct remittance. (This situation may arise if the individual first becomes eligible for social security benefits after December 31, 1981, and is, therefore, not eligible for the fixed minimum, or receives age 72 special benefits that are reduced because the individual receives a government pension.)

(ii) If the monthly railroad retirement benefit or civil service annuity payment is less than the premium, the monthly payment is not withheld and the enrollee is required to pay the total premium by direct remittance.

(b) *Priorities for payment.* (1) If an enrollee is enrolled under a State buy-in agreement—

(i) SMI premiums may not be deducted from monthly cash benefits or annuities; and

(ii) The enrollee may not be required to pay by direct remittance.

(2) If an enrollee is not covered under a State buy-in agreement, but is receiving a monthly benefit or an annuity specified in paragraph (a)(1)(ii) of this section—

(i) The premiums are deducted from that benefit or annuity; or

(ii) If the monthly benefit or payment is less than the monthly premium, the rules of paragraph (a)(2) of this section apply.

(3) If an enrollee is neither covered under a State buy-in agreement, nor receiving monthly benefits or annuity payments, the premiums must be paid totally by direct remittance.

(c) *Payment by a State under a buy-in agreement.* (1) A buy-in agreement is an agreement under which a State, through enrollment and payment of SMI premiums, secures SMI benefits for individuals who are eligible for that program and also eligible for certain other cash or medical benefits. (Policies on enrollment under State buy-in agreements are contained in Subpart B of Part 405 of this chapter.)

(2) The State pays the premiums for each month for which an individual is covered under the agreement.

(3) If an individual's coverage under a State buy-in agreement terminates, his coverage continues on an individual enrollment basis. The premiums are then deducted from benefits, as set forth in Subpart C of this part, or paid by direct remittance in accordance with Subpart D or Subpart E of this part.

(4) Policy on collection of premiums from buy-in States is set forth in a FEDERAL REGISTER notice published on September 30, 1985 at 50 FR 39784.

§ 408.8 Grace period and termination date.

(a) *Grace period.* (1) For all initial premium payments (monthly or quarterly), and subsequent monthly payments, the grace period ends with the last day of the third month after the billing month.

(2) For subsequent quarterly payments, the grace period ends with the last day of each 3-month period for which the enrollee is billed.

(3) For payments that are required because of suspension of monthly benefits, the grace period ends the last day of the fourth month after the end of the enrollee's taxable year.

(4) For payments required because the monthly benefit is less than the monthly premium, the grace period ends on April 30 of the year following the calendar year for which the premiums are due.

(b) *Extension of grace period: Last day is nonwork day.* If the last day of the grace period is a Saturday, Sunday, legal holiday, or a day that, by statute or executive order, is a nonwork day for Federal employees, the grace period is extended to the next succeeding work day.

(c) *Termination date.* The end of the grace period is the termination date for SMI coverage if overdue premiums have not been paid by that date in accordance with § 408.68.

(d) *Extension of grace period for good cause.* (1) HCFA may reinstate entitlement, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within three calendar months after the termination date.

(2) Good cause will be found if the individual establishes, by a credible statement, that failure to pay premiums within the initial grace period was due to conditions over which he or she had no control, or which he or she could not reasonably have been expected to foresee.

§ 408.10 Claim for monthly benefits pending concurrently with request for SMI enrollment.

(a) If it is clear that an individual who applies for social security or railroad retirement benefits and for SMI will be entitled to monthly benefits, the application for monthly benefits is processed simultaneously with the request for SMI enrollment.

(1) If monthly benefits are paid, the SMI premiums are deducted from those benefits.

(2) If monthly benefits are suspended (for instance, because the individual's earnings exceed the maximum allowed by law), the enrollee is billed for direct remittance.

(b) If it is clear that an individual will be entitled to SMI, but there is substantial question as to eligibility for monthly benefits, the request for SMI enrollment is processed separately.

(1) When SMI enrollment is approved, the enrollee is billed for direct remittance.

(2) When the application for monthly benefits is adjudicated, the following rules apply:

(i) If monthly benefits are paid, the SMI premiums are deducted from those benefits, with appropriate adjustments for any premiums already paid by direct remittance.

(ii) If the application for monthly benefits is approved but the benefits are suspended, the grace period is as set forth in § 408.8(a)(3).

(iii) If the application for monthly benefits is denied, the grace period is as set forth in § 408.8(a)(1).

Subpart B—Amount of Monthly Premiums

§ 408.20 Standard monthly premium.

(a) *Basic provisions.* (1) The law established a monthly premium of $3 for the initial period of the program. It also set forth criteria and procedures for the Secretary to follow each December, beginning with December 1968, to determine and promulgate the standard monthly premium for the 12-month period beginning with July of the following year.

(2) The law was amended in 1983 to require that the Secretary promulgate the standard monthly premium in September of that year, and each year thereafter, to be effective for the 12 months beginning with the following January.

(3) The standard monthly premium applies to individuals who enroll during their initial enrollment periods. In other situations, that premium may

be increased or decreased as specified in this subpart.

(b) *Criteria and procedures for the period from July 1976 through December 1983, and for periods after December 1988.* (1) For periods from July 1976 through December 1983, the Secretary determined and promulgated as the standard monthly premium (for disabled as well as aged enrollees) the lower of the following:

(i) The actuarial rate for the aged.

(ii) The monthly premium promulgated the previous December for the year beginning July 1, increased by a percentage that is the same as the latest cost-of-living increase in old age insurance benefits that occurred before the current promulgation. (Because of the change in the effective dates of the premium amount (under paragraph (a)(2) of this section), there was no increase in the standard monthly premium for the period July 1983 through December 1983.)

(2) For periods after December 1988, the Secretary will determine the standard monthly premium in the manner specified in paragraph (b)(1) of this section, but promulgate it in September, for the following calendar year.

(c) *Premiums for calendar years 1984 through 1988.* For calendar years 1984 through 1988, the standard monthly premium for all enrollees—

(1) Is equal to 50 percent of the actuarial rate for enrollees age 65 or over, that is, is calculated on the basis of 25 percent of program costs without regard to any cost-of-living increase in old age insurance benefits; and

(2) Is promulgated in the preceding September.

(d) *Special provisions for calendar years 1987 and 1988*—(1) *Limitation on increase of standard premium.* If there is no cost-of-living increase in old age insurance benefits or disability insurance benefits effective for December 1986, or December 1987, the standard monthly premium for the succeeding year is not increased.

(2) *Nonstandard premiums for certain cases.* (i) A nonstandard premium may be established in individual cases if the following conditions are met:

(A) The individual is entitled to old age or disability benefits for the months of November and December, and actually receives the coresponding benefit checks in December and January.

(B) There is a cost-of-living increase in old age or disability benefits but, wholly or partly because of an increase in the standard monthly premium, the beneficiary would receive a lower cash benefit in January than he or she received in December.[1] (To the extent that a benefit reduction is the result of any factor other than the premium increase, the nonstandard premium provision does not apply.)

(ii) The nonstandard premium is the greater of the following:

(A) The premium paid for December.

(B) The standard premium promulgated for January, reduced as necessary to compensate for the fact that the cost of living increase was less than the increase in the standard premium.

(iii) A nonstandard premium established under paragraph (d)(2)(ii) of this section continues in effect for the rest of the calendar year even if later there are retroactive adjustments in benefit payments. (The only thing that could affect the nonstandard premium is a determination that the individual had not established, or had lost, entitlement to monthly benefits for November or December.)

(iv) A nonstandard premium is subject to increase for late enrollment or reenrollment as required under other sections of this subpart. The increase is based on the amount of the standard premium and added to the nonstandard premium.

§ 408.22 Increased premiums for late enrollment and for reenrollment.

For an individual who enrolls after expiration of his or her initial enrollment period or reenrolls after termination of a coverage period, the standard monthly premium determined under

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[1] Cost-of-living increases are effective in December, and premium increases are effective in January. However, since premiums for each month are collected in the preceding month, both increases affect the amount of the check for December, which is mailed in January.

§ 408.20 is increased by ten percent for each full twelve months in the periods specified in §§ 408.24 and 408.25.

§ 408.24 Individuals who enrolled or reenrolled before April 1, 1981 or after September 30, 1981.

(a) *Enrollment.* For an individual who first enrolled before April 1, 1981 or after September 30, 1981, the period *includes* the number of months elapsed between the close of the individual's initial enrollment period and the close of the enrollment period in which he or she first enrolled, and *excludes* the following:

(1) The three months of January through March 1968, if the individual first enrolled before April 1968.

(2) Any months before January 1973 during which the individual was precluded from enrolling or reenrolling by the 3-year limitation on enrollment or reenrollment that was in effect before October 30, 1972.

(3) Any months in or before a period of coverage under a State buy-in agreement.

(4) For an individual under age 65, any month before his or her current continuous period of entitlement to hospital insurance.

(5) For an individual age 65 or older, any month before the month he or she attained age 65.

(6) For premiums due for months beginning with September 1984 and ending with May 1986, the following:

(i) Any months after December 1982 during which the individual was—

(A) Age 65 to 69;

(B) Entitled to hospital insurance (Medicare Part A); and

(C) Covered under an employer group health plan by reason of current employment in accordance with § 405.340 of this chapter.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in section 2338(b) of Pub. L. 98-369 and § 405.216 of this chapter.

(7) For premiums due for months beginning with June 1986, the following:

(i) Any months after December 1982 during which the individual was:

(A) Age 65 or over; and

(B) Covered, by reason of current employment, under an employer group health plan that meets the definition of § 162(i)(3) of the Internal Revenue Code of 1954.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in section 2338 of Pub. L. 98-369, or section 9219(b) of Pub. L. 99-272 and § 405.216 of this chapter.

(8) For premiums due for months beginning with January 1987, the following:

(i) Any months after December 1986 and before January 1992 during which the individual was:

(A) A disabled Medicare beneficiary under age 65;

(B) Not eligible for Medicare on the basis of end stage renal disease, under § 406.13 of this chapter; and

(C) Covered, as an employee, employer, individual associated in a business relationship with an employer, or family member of any of the foregoing, under an employer group health plan meeting the definition in § 5000(b) of the Internal Revenue Code of 1954.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in section 9319(c) of Pub. L. 99-509 and § 405.216 of this chapter.

(b) *Reenrollment.* For an individual who reenrolled before April 1, 1981 or after September 30, 1981, the period:

(1) *Includes* the following:

(i) The number of months elapsed between the close of the individual's initial enrollment period and the close of the enrollment period in which he or she first enrolled; plus

(ii) The number of months elapsed between the individual's initial period of coverage and the close of the enrollment period in which he or she reenrolled; plus

(iii) The number of months elapsed between each subsequent period of coverage and the close of the enrollment period in which he or she reenrolled.

(2) *Excludes* the following:

(i) The periods specified in paragraphs (a)(1) through (a)(8) of this section; and

(ii) Any month before April 1981 during which the individual was precluded from reenrolling by the two-enrollment limitation in effect before that date.

[52 FR 48118, Dec. 18, 1987, as amended at 53 FR 6648, Mar. 2, 1988]

§ 408.25 Individuals who enrolled or reenrolled between April 1 and September 30, 1981.

(a) *Basic rules.* Except as specified in paragraph (b) of this section, the rules set forth in § 408.24 apply to an individual who enrolled or reenrolled between April 1 and September 30, 1981.

(b) *Exception.* For an individual who enrolled or reenrolled between April 1 and September 30, 1981, the months to be counted ran through the month in which he or she reenrolled. (During those 6 months, continuous open enrollment was in effect and there was no 3-month "general enrollment period".)

§ 408.26 Examples.

Example 1. Mr. J, who became age 65 and otherwise eligible for enrollment in November 1965, first enrolls in March 1968. The months to be included in determining the amount of the increase in Mr. J's premiums begin with June 1966 (the first month after the close of his initial enrollment period) and extend through December 1967 (the period January through March of 1968 is excluded in determining the total months) for a total of 19 months. Since there is only one full 12-month period in 19 months, Mr. J's premiums will be 10 percent greater than if he had enrolled in his initial enrollment period.

Example 2. Mr. V, who enrolled in December 1965, voluntarily terminates his enrollment effective midnight December 31, 1967. He enrolls for a second time in January 1969. The months to be included in determining the amount of the increase in Mr. V's premiums are January 1968 through March 1969, a total of 15 months. Since this totals one full 12-month period. Mr. V's monthly premium, will be increased by 10 percent.

Example 3. Ms. N becomes age 65 in July 1965 and first enrolls in December 1967. She pays premiums increased by 10 percent above the regular rate, beginning July 1968, the first month of her SMI coverage. Ms. N fails to pay the premiums for the calendar quarter ending June 30, 1970, and her coverage is terminated on that date, the end of her grace period. Ms. N enrolls for a second time in January 1971. The months to be included in determining the amount of the increase in Ms. N's premiums are June 1966 through December 1967, a total of 19 months, and July 1970 through March 1971, a total of 9 months, for a grand total of 28 months. Since this totals two full 12-month periods, Ms. N's monthly premium will be increased by 20 percent.

Example 4. Mr. X attained age 65 in August 1966 and enrolled during his initial enrollment period. His coverage was terminated effective June 30, 1968, for nonpayment of premiums. He reenrolls in March 1973. For purposes of computing any applicable premium increase, he will not be charged any months between March 1971 (the end of the last general enrollment period during which he was eligible to reenroll under the law in effect before October 30, 1972) and January 1973. Therefore, he will be charged 36 months (July 1968–March 1971 plus January 1973-March 1973) and his premiums for his second period of coverage will be increased 30 percent.

Example 5. Ms. C, who attained age 65 in August 1973, had two periods of supplementary medical insurance coverage, both of which were terminated because of nonpayment of premiums: August 1973 through April 1975 and July 1977 through August 1978. She reenrolls in July 1981. The months to be included in determining the amount of premium increase are May 1975 through March 1977 (23 months) and April 1981 through July 1981 (4 months) for a total of 27 months. The 31 months from September 1978 through March 1981 may not be counted because Ms. C was prevented from reenrolling by the two-enrollment limitation in effect before April 1, 1981. For Ms. C, the standard monthly premium would be increased by 20 percent.

[52 FR 48115, Dec. 18, 1987; 53 FR 4150, Feb. 12, 1988]

§ 408.27 Rounding the monthly premium.

Any monthly premium that is not a multiple of 10 cents is rounded to the nearest multiple of 10 cents, and any odd mulitple of 5 cents is rounded to the next higher multiple of 10 cents.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

Subpart C—Deduction From Monthly Benefits

§ 408.40 Deduction from monthly benefits: Basic rules.

(a) *Deduction from monthly benefits.* (1) Enrollees who are receiving monthly benefits do not have the option of paying by direct remittance to avoid deduction.

(2) If the enrollee is entitled to more than one type of monthly benefit, the order of priority for deduction is as follows:

(i) Railroad retirement benefits.

(ii) Social security benefits.

(iii) Civil service annuities.

(b) *Deduction from initial or reinstated benefits.* When an enrollee receives a monthly benefit check after an initial award or after a period of suspension, that check is, if administratively feasible, reduced or increased to deduct unpaid premiums or refund premiums paid in advance by direct remittance.

(c) *Ongoing deductions.* The premium for each month is deducted from the cash benefit for the preceding month, e.g., the premium for March is deducted from the benefit for February, which is paid at the beginning of March.

§ 408.42 Deduction from railroad retirement benefits.

(a) *Responsibility for deductions.* If an enrollee is entitled to railroad retirement benefits, his or her SMI premiums are deducted from those benefits by the Railroad Retirement Board (RRB) even though he or she is also entitled to social security benefits or a civil service annuity, or both.

(b) *Action when benefits are suspended.* If the railroad retirement benefits are suspended, the RRB sends premium notices requesting direct remittance, to be made in accordance with the rules set forth in Subpart D of this part.

§ 408.43 Deduction from social security benefits.

SSA, acting as HCFA's agent, deducts the premiums from the monthly social security benefits if the enrollee is not entitled to railroad retirement benefits. (If the benefit is less than the monthly premium, the benefit is withheld and the enrollee is required to pay the balance through direct remittance.)

§ 408.44 Deduction from civil service annuities.

(a) *Responsibility for deductions.* If an enrollee is not entitled to railroad retirement benefits or social security benefits, and is receiving a civil service annuity, the premiums are deducted from that annuity by the Office of Personnel Management (OPM) on the basis of a notice from SSA indicating that the annuitant is entitled to SMI.

(b) *Deduction of spouse's premiums.* If the annuitant's spouse is also enrolled for SMI and is not entitled to a civil service annuity or to social security or railroad retirement benefits, and the annuitant gives written consent, OPM also deducts the spouse's premium from the annuitant's monthly check.

(c) *Withdrawal of annuitant's consent.* (1) If an annuitant wishes to withdraw consent for deduction of the spouse's premium, he or she must send written notice of withdrawal to OPM.

(2) The withdrawal notice is effective with the third month after the month in which it is received, or with the month specified in the notice, whichever is later.

§ 408.45 Deduction from age 72 special payments.

(a) *Deduction of premiums.* SMI premiums are deducted from age 72 special payments made under section 228 of the Act or the payments are withheld under procedures that correspond to the rules set forth in §§ 408.40 and 408.43.

(b) *Collection of premiums while age 72 special payments are suspended.* If the age 72 special payments are suspended, HCFA or its agent notifies the enrollee to pay premiums by direct remittance, in accordance with the rules set forth in § 408.60.

(c) *Grace period.* The grace period ends with the last day of the third month after the billing month.

(d) *Resumption of age 72 special payments.* (1) If age 72 special payments are resumed before the end of the grace period and all premium arrears can be deducted from those special payments, SMI coverage continues and the enrollee need not pay by direct remittance.

(2) Subsequent special payments are reduced by the amount of the premium for as long as the enrollee receives special payments.

§ 408.46 Effect of suspension of social security benefits.

(a) *Benefit payments to be resumed during the taxable year.* (1) If social security benefit payments are scheduled to be resumed during the enrollee's current taxable year, the enrollee is not billed.

(2) The enrollee may, if he or she wishes, pay the premiums during suspension of benefits.

(b) *Benefit payments not to be resumed during the enrollee's current taxable year.* (1) If social security benefits are suspended for a period that will not permit collection of all premiums due from monthly benefits payable in the enrollee's current taxable year, HCFA or its agents bill the enrollee and require direct remittance in accordance with Subpart D of this part.

(2) The first billing is for whatever premiums are necessary to place the enrollee in a quarterly cycle.

(3) Thereafter, the billing is on a quarterly basis. (Quarters for different enrollees are staggered throughout the year.)

(4) The enrollee has the option of paying premiums for more than one quarter at the same time.

§ 408.47 Overdue premiums for months in a closed taxable year.

(a) *Reasons for overdue premiums.* An enrollee may have overdue premiums for a closed taxable year for either of the following reasons:

(1) The monthly social security benefits were suspended.

(2) The request for SMI enrollment was adjudicated with coverage retroactive to the enrollee's previous taxable year.

(b) *Payment of overdue premiums for a closed taxable year.* (1) If the premiums are overdue because of suspension of social security benefits—

(i) The enrollee is billed at the end of his or her taxable year; and

(ii) The grace period ends with the last day of the fourth month after the close of the enrollee's taxable year.

(2) If the premiums are overdue because SMI enrollment was adjudicated with retroactive coverage and cannot be collected from past due or current monthly benefits—

(i) The enrollee is billed immediately after adjudication; and

(ii) The grace period ends with the last day of the third month after the billing month.

(3) The bill indicates that, unless the arrears are paid by the last day of the grace period, coverage will end on that day.

(c) *Example.* Mr. H became entitled to supplementary medical insurance effective July 1980. He was entitled to monthly benefits, but reported work and earnings which precluded payment of those monthly benefits. Although billed, he paid no premium by direct remittance. Mr. H's taxable year ends May 31 because he reports his earnings for fiscal years ending on that date. Early in May 1981, Mr. H is notified of his unpaid premiums ($105.60) for the fiscal year ending May 31, 1981, and advised that those premiums are overdue and should be paid promptly. Without good cause, Mr. H fails to pay by September 30, 1981, despite the May notice advising him that the termination date is September 30. Mr. H's supplementary medical insurance coverage is terminated effective midnight September 30, 1981.

§ 408.50 When premiums are considered paid.

(a) *Actual deduction.* A premium is considered paid if it is actually deducted from a monthly benefit check. Therefore—

(1) The premium is "paid" even if SSA later finds that the benefit was paid in error; but

(2) A finding that a monthly benefit was erroneously withheld does not constitute payment of the premium for that month. Since there was no payment, there was no deduction. The enrollee is billed and continuance of coverage depends on payment of premiums before the end of the grace period or extended grace period.

(b) *Payment within the grace period.* Overdue premiums are considered paid within the grace period in the following situations:

(1) *Benefits are resumed during the grace period.* (i) Monthly cash benefit payments are payable for the last month of the initial grace period or for earlier months on the basis of a notice filed by the enrollee before the initial grace period ends; and

(ii) Those payments are sufficient to permit deduction of all overdue premiums.

(2) *Annual accounting report or other report submitted during the grace period shows a benefit is due.* (i) Before the end of the grace period, the enrollee submits a report clearly showing that monthly cash benefits, previously withheld, are payable for one or more months of a closed taxable year; and

(ii) Those benefits are sufficient to permit deduction of the full amount of the overdue premiums.

(3) Premium arrears are paid by direct remittance. The enrollee makes a direct remittance payment of all overdue premiums before the end of the grace period.

(c) *Examples.* (1) Mr. C, who became entitled to SMI in July 1978, was entitled to monthly social security benefits of $300. His premium rate was $8.20. He was paid $291.80 for each month from July to December 1978. In 1979, SSA determined that Mr. C's work and earnings in *1978* precluded any benefit payments for that year. Mr. C would not be found to owe any premiums for July through December 1978. He would, of course, have to refund the full $300 a month overpayment to SSA.

(2) (i) Ms. M also became entitled in July 1978. On the basis of Ms. M's report of work and earnings, her monthly benefits for July through December 1978 were withheld and SMI premiums could not be deducted. She was billed but made no premium payments during 1978. In January 1979, Ms. M was notified of the overdue premiums for her closed taxable year and of the fact that her SMI coverage would terminate April 30, 1979 unless the overdue premiums are paid by then. Ms. M's monthly benefits continue suspended and she fails to pay the premiums. Consequently, her SMI coverage is terminated as of April 30, 1979. In March 1980, Ms. M submits an annual report that she did not work in December 1978. A benefit for that month is paid subsequently.

(ii) If Ms. M had submitted the report of the benefit due before the end of the grace period (April 30, 1979), it would have permitted deduction of all her overdue premiums and continuation of SMI coverage. Because the report was not submitted before April 30, 1979, Ms. M's coverage cannot be reinstated.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.52 Change from direct remittance to deduction.

If a direct remittance enrollee becomes entitled to monthly benefits—

(a) The SMI premiums are deducted from those benefits; and

(b) The enrollee is notified of the deduction and of any adjustment of the initial benefit check that is required to collect overdue premiums or refund premiums paid in advance.

§ 408.53 Change from partial direct remittance to full deduction.

If a benefit that was less than the premium (and therefore required direct remittance of the difference) is increased to an amount equal to, or greater than, the premium—

(a) The full premium is paid from the benefit; and

(b) Any amounts the enrollee had paid toward premiums not yet due are refunded.

Subpart D—Direct Remittance: Individual Payment

§ 408.60 Direct remittance: Basic rules.

(a) Premiums not deducted from monthly benefits under Subpart C of this part or paid by a State buy-in agreement must be paid by direct remittance to HCFA or its agents, by or on behalf of the enrollee.

(b) Quarterly payment is preferred as more cost-effective, but monthly payment is accepted if the enrollee is unwilling or unable to make quarterly payments or is also paying hospital insurance premiums, which must be paid every month.

(c) HCFA, directly or through its agents, sends quarterly or monthly premium bills and includes an addressed return envelope with the bill.

(d) The individual must—

(1) Send a check or money order that is drawn payable to "HCFA Medicare Insurance" and show the enrollee's name and claim number as it appears on the Medicare card; and

(2) Return the bill with the check or money order in the preaddressed envelope.

§ 408.62 Initial and subsequent billings.

(a) *Monthly billing.* (1) The first premium bill is for the period from the first month of coverage (or the first month of change from deduction or State buy-in payment) through the end of the first month after the month of billing.

(2) Subsequent billings are for periods of one month.

(b) *Quarterly billing.* (1) The first premium bill is for the period from the first month of coverage (or of change from deduction or State buy-in payment) through the third month after the month of billing.

(2) Subsequent billings are for periods of three months.

§ 408.63 Billing procedures when monthly benefits are less than monthly premiums.

If monthly benefits are less than monthly premiums, the following procedures apply:

(a) *Notice of amount due.* At the beginning of SMI entitlement, and at the beginning of each succeeding calendar year, SSA—

(1) Notifies the enrollee of the amount of benefits payable for the rest of the year and the total premiums due for those same months; and

(2) Bills the enrollee for the difference.

(b) *Notice of amount overdue.* At the beginning of each succeeding calendar year, SSA—

(1) Notifies the enrollee of any amounts overdue for premiums for the preceding calendar year; and

(2) Indicates that if the amount still overdue on April 30 is equal to or greater than the premium for 3 months, SMI coverage will terminate on that date.

§ 408.65 Payment options.

(a) The enrollee is not asked to pay premiums at the time of enrollment but is instructed to pay them upon receipt of a premium bill from HCFA or its agents.

(b) However, if the enrollee wishes, he or she may pay from one to 12 months or from one to four quarters at the time of enrollment.

§ 408.68 When premiums are considered paid.

(a) *Payment by check.* The premium is considered paid if the check is paid by the bank the first or second time it is presented for payment.

(b) *Payment within the grace period.* (1) A premium is considered paid within the grace period if it is delivered personally, or mailed on or before the last day of that period.

(2) A premium payment is considered to have been mailed 7 days before it is received by HCFA.

§ 408.70 Change from quarterly to monthly payments.

If an enrollee requests change from quarterly to monthly payment—

(a) If the enrollee is paid up under the quarterly cycle, the first monthly bill is for one month.

(b) If the enrollee is not paid up under the quarter system, the first bill includes all premiums due.

§ 408.71 Change from deduction or State payment to direct remittance.

(a) *Basis for change.* An SMI enrollee is required to pay by direct remittance in any of the following circumstances:

(1) The enrollee's entitlement to social security or railroad retirement benefits ends for any reason other than death.

(2) The premiums can no longer be deducted from the civil service annuity of the enrollee or the enrollee's spouse.

(3) The enrollee no longer qualifies for coverage under a State buy-in agreement, and is not entitled to social security or railroad retirement monthly benefits.

(b) *Billing.* When any of the events specified in paragraph (a) of this section occurs (or as soon thereafter as possible), HCFA or its agents bill the enrollee for direct remittance, in accordance with this subpart.

Subpart E—Direct Remittance: Group Payment

§ 408.80 Basic rules.

(a) *Sources of group payment.* An employer, a lodge, union, or other organization may pay SMI premiums on behalf of one or more enrollees.

(b) *Informal arrangement.* Enrollees may turn over their premium notices to their employer, union, lodge, or other organization and that organization may send a single payment (with the premium notices attached so that the payments can readily be identified with the appropriate enrollees) to the HCFA Premium Collection Center. Prompt payment is essential since SMI coverage terminates if premiums are not paid by the end of the grace period.

(c) *Group billing arrangement.* HCFA may send a single notice for the premiums due from a group of enrollees if the following conditions are met:

(1) The group payer—

(i) Uses funds other than the enrollees' to pay all or a substantial part of the premiums; or

(ii) Deducts the premiums from periodic payments it makes to the enrollees in the group.

(2) The enrollee's rights are protected and enrollees are not required to pay the costs of having their premiums paid on a group basis.

§ 408.82 Conditions for group billing.

HCFA agrees to a group billing arrangement only if the following conditions are met:

(a) Conditions the group payer must meet. The group payer submits a written request for group billing—

(1) Showing that all or part of the payments are made from the payer's funds or from funds due the enrollees and in the payer's possession; and

(2) Agreeing not to charge the enrollees for the service of paying the premiums or for the administrative costs such as recordkeeping and postage.

(b) *Enrollees eligible for group payment.* (1) Group payment may be made only on behalf of individuals who are already enrolled and are being billed for direct remittance.

(2) Group payment may not be made for enrollees whose premiums are being deducted from monthly benefits in accordance with Subpart C of this part or being paid by the State under a buy-in agreement.

(c) *Protection of enrollee's rights.* The use of group billing must not jeopardize the enrollees' right—

(1) To confidentiality of personal information;

(2) To terminate enrollment;

(3) To resume individual payment of premiums if he or she wishes; and

(4) To receive notice of any action that affects the SMI benefits.

(d) *Authorization by the enrollee.* (1) To ensure maximum feasible protection of the rights specified in paragraph (c) of this section, each enrollee must give written authorization as specified in § 408.84(a)(2).

(2) A group payer that is not an entity of State or local government must submit all enrollee authorizations to HCFA.

(3) A group payer that is an entity of State or local government may retain the authorizations and certify to HCFA that it has on file an authorization for each enrollee included in the group.

(4) It is on the basis of the enrollee's authorization that HCFA sends the group payer information about each enrollee, as necessary to carry out the group payment function.

(e) *Size of group.* The number of enrollees must be at least 20, which is the minimum size sufficient to make group billing efficient. (Smaller groups may use the informal procedure described in § 408.80(b).)

§ 408.84 Billing and payment procedures.

(a) *Initial premium notice.* (1) HCFA or its agent always sends the initial premium notice to the enrollee.

(2) An enrollee who wishes to have the premiums paid on a group basis must give the notice to the group payer, along with written authorization for sending subsequent notices to the group payer and for release of the information required for the group payment process.

(b) *Monthly billings.* Group premiums are billed on a monthly basis. However, the group payer may pay up to 12 months in advance.

(c) Group payers must make their payments within 30 days after billing, to avoid infringing on the 90-day grace period during which the premiums may be paid by the enrollee if he or she is dropped from the group.

(d) *Effect of group payment.* Payment by a group payer is considered payment by the enrollee.

§ 408.86 Responsibilities under group billing arrangement.

(a) *Enrollee responsibilities.* (1) The enrollee is still responsible for premium payments; the group payer simply acts as his agent. If the agent fails to pay, or identifies the payment incorrectly, SSA notifies both the agent and the enrollee that the enrollee's account is delinquent. If an enrollee fails to take action on that notice, entitlement is terminated for nonpayment of premiums.

(2) The enrollee must promptly notify both SSA and the group payer of any change of address.

(b) *Group payer's responsibilities.* The group payer must—

(1) Make premium payments promptly upon receipt of notices;

(2) Promptly notify both HCFA and the enrollee when it drops an enrollee from the group;

(3) Make payments in a way that facilitates efficient and economical processing; and

(4) Maintain the confidentiality of the personal information obtained from HCFA for the group payment process.

(c) *HCFA responsibilities.* HCFA—

(1) Sends the bill to the group payer upon authorization from the enrollee;

(2) Notifies both the payer and the enrollee if the payer fails to make timely payments; and

(3) Refunds excess premiums in accordance with § 408.88.

§ 408.88 Refund of group payments.

(a) *Basis for refund.* Group payments are refunded only in the following circumstances:

(1) The premium was for a month after the month in which the enrollee's SMI coverage terminated or the enrollee died.

(2) The premium was for a month after the month in which the group payer gave notice (before the 26th day of that month) that the enrollee was no longer eligible for group payment and was being dropped from the group.

(b) *Example.* F is the wife of J who is a retiree of Corporation X. That corporation pays premiums on behalf of all of its retirees and their dependents. F obtains a divorce from J on October 20 and thus disqualifies herself for further premium payments by the corporation. The corporation gives notice on November 10 that a refund is due because F has been dropped from the list of persons for whom it has agreed to pay premiums. The premium paid for December would be refunded to the group payer.

(c) *To whom refund is made.* (1) HCFA ordinarily refunds to the group payer the premiums specified in paragraph (a) of this section.

(2) However, if HCFA has information that clearly shows those premiums were paid from the enrollee's funds, it sends the refund to the enrollee.

§ 408.90 Termination of group billing arrangement.

(a) A group billing arrangement may be terminated either by the group payer or by HCFA upon 30 days' notice.

(b) HCFA may terminate the arrangement if it finds that the group payer is not acting in the best interest of the enrollees or that, for any other reason, the arrangement has proved inconvenient for HCFA.

§ 408.92 Change from group payment to deduction or individual payment.

(a) *Enrollee excluded from group payment arrangement because of entitlement to monthly benefits.* (1) When an enrollee becomes entitled to monthly benefits from which premiums can be deducted as specified in Subpart C of this part, HCFA notifies the group payer to discontinue payment for that enrollee.

(2) In order to maintain confidentiality, HCFA does not explain to the group payer the reason for excluding the enrollee from the group payment arrangement.

(3) The enrollee's premiums are thereafter deducted from the monthly benefits, in accordance with Subpart C of this part.

(b) *Enrollee no longer eligible for the group.* (1) When an enrollee is no longer eligible to be included in the group (for instance because he or she is no longer employed by the group payer or has terminated union or lodge membership), the group payer must promptly notify HCFA and the enrollee.

(2) HCFA or its agents resume sending individual bills to the enrollee, for direct remittance subject to the grace period and termination dates specified in § 408.8.

Subpart F—Termination and Reinstatement of Coverage

§ 408.100 Termination of coverage for nonpayment of premiums.

(a) *Effective date of termination.* Termination is effective on the last day of the grace period. The determination is not made until 15 days after that day to allow for processing of remittances mailed late in the grace period, as provided in § 408.68.

(b) *Notice of termination.* (1) SSA sends the enrollee notice of termination between 15 and 30 days after the end of the grace period and includes information regarding the enrollee's right of appeal.

(2) HCFA notifies any intermediary or carrier that had previously been informed that the enrollee had met the SMI deductible for the year in which the termination is effective.

§ 408.102 Reconsideration of termination.

(a) *Basic rules.* Coverage may be reinstated without interruption of benefits if the following conditions are met:

(1) The enrollee appeals the termination by the end of the month following the month in which SSA sent the notice of termination.

(2) The enrollee alleges and it is found that the enrollee did not receive timely and adequate notice that the premiums were overdue.

(3) The enrollee pays, within 30 days after SSA's subsequent request for payment, all premiums due through the month in which he or she appealed the termination.

(b) *Basis for reinstating coverage.* Coverage may be reinstated if the evidence establishes one of the following:

(1) The enrollee acted diligently to pay the premiums or to request relief upon receiving a premium notice very late in the grace period or shortly after its end, and the delayed notice was not the enrollee's fault. (For example, if the billing notice was misaddressed or lost in the mail, it would not be the enrollee's fault; if the enrollee had moved and not notified SSA of the new address, he or she would be responsible for the delay.)

(2) On the basis of information given by SSA, the enrollee could reasonably have believed that the premiums were being paid by deduction from benefits or by some other means. (An example would be a notice indicating that premiums would be paid by a State Medicaid agency or a group payer or would be deducted from the spouse's civil service annuity.)

(c) *No basis for reinstating coverage.* Coverage may not be reinstated if the enrollee—

(1) Received timely and adequate notice but failed to pay within the grace period, for example because of insufficient income or resources; or

(2) Appealed the termination more than one month after the month in which SSA sent the termination notice.

§ 408.104 Reinstatement procedures.

(a) *Request for payment.* If the conditions of § 408.102(a) (1) and (2) are met, SSA sends written notice requesting the enrollee to pay, within 30 days, all premiums due through the month in which the enrollee appealed the termination.

(b) *Reinstatement of coverage.* If SSA receives the requested payment within 30 days, it sets aside the termination and reinstates the enrollee's coverage without interruption.

Subpart G—Collection of Unpaid Premiums; Refund of Excess Premiums After the Death of the Enrollee

§ 408.110 Collection of unpaid premiums.

(a) *Basis and scope*—(1) *Basis.* Under the Federal Claims Collection Act of 1966 (31 U.S.C. 3711), HCFA is required to collect any debts due it but is authorized to suspend or terminate collection action on debts of less than $20,000 when certain conditions are met. (See 4 CFR, Parts 101-105 for general rules implementing the Federal Claims Collection Act.) As indicated in § 408.4, unpaid premiums are debts owed the Federal government by the enrollee or the enrollee's estate.

(2) *Scope.* This section sets forth the methods of collection used by HCFA and the circumstances under which HCFA terminates or renews collection action. The regulations in this section apply to hospital insurance premiums as well as SMI premiums.

(b) *Collection of unpaid premiums.* Generally, HCFA will attempt to collect unpaid premiums by one of the following methods:

(1) By billing enrollees who pay the premiums directly to HCFA or to a designated agent in accordance with § 408.60.

(2) By deduction from any benefits payable to the enrollee or the estate of a deceased enrollee under Title II or XVIII of the Social Security Act, the Railroad Retirement Act or any act administered by the Office of Personnel Management in accordance with § 408.4(b) and Subpart C of this part (Deduction from Monthly Benefits); or

(3) By billing the estate of a deceased enrollee.

(c) *Termination of collection action.* HCFA terminates collection action on unpaid premiums under either of the following circumstances, if the cost of collection exceeds the amount of overdue premiums:

(1) The individual is not entitled to benefits under the Acts listed in paragraph (b)(2) of this section, is not currently enrolled for SMI or premium hospital insurance, and demonstrates, to HCFA's satisfaction, that he or she is unable to pay the debt within a reasonable time.

(2) The individual has been dead more than 27 months (the maximum time allowed for claiming SMI benefits), and the legal representative of his or her estate demonstrates, to HCFA's satisfaction, that the estate is unable to pay the debt within a reasonable time.

(d) *Renewal of collection efforts.* HCFA renews collection efforts in either of the following circumstances, if the cost of collection does not exceed the amount of the overdue premiums:

(1) The individual enrolls again for premium hospital insurance or SMI. (Payment of overdue premiums is not a prerequisite for reenrollment.)

(2) The individual becomes entitled or reentitled to social security or railroad retirement benefits or a Federal civil service annuity.

§ 408.112 Refund of excess premiums after the enrollee dies.

If HCFA has received premiums for months after the enrollee's death, HCFA refunds those premiums as follows:

(a) To the person or persons who paid the premiums or, if the premiums were paid by the enrollee, to the representative of the enrollee's estate, if any.

(b) If refund cannot be made under paragraph (a) of this section, HCFA refunds the premiums to the enrollee's survivors in the following order of priority:

(1) The surviving spouse, if he or she was either living in the same household with the deceased at the time of death, or was, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(2) The child or children who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(3) The parent or parents who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent);

(4) The surviving spouse who was not living in the same household with the deceased at the time of death and was not, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(5) The child or children who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(6) The parent or parents who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent).

If none of the listed relatives survives, no refund can be made.

PART 409—HOSPITAL INSURANCE BENEFITS

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AUTHORITY: Secs. 1102, 1812, 1813, 1861, 1862(h), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395d, 1395e, 1395x, 1395y(h), 1395hh, and 1395rr).

SOURCE: 48 FR 12541, Mar. 25, 1983, unless otherwise noted.

Subpart A—Hospital Insurance Benefits: General Provisions

§ 409.1 Statutory basis.

Sections 1812 and 1813 of the Social Security Act establish the scope of benefits of the hospital insurance program under Medicare Part A and set forth the deductible and coinsurance requirements.

§ 409.2 Scope.

Subparts A through G of this part describe the benefits available under Medicare Part A and set forth the limitations on those benefits, including certain amounts of payment for which beneficiaries are responsible.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.3 Definitions.

As used in this part, unless the context indicates otherwise—

"Arrangements" means arrangements which provide that Medicare payment made to the provider that arranged for the services discharges the liability of the beneficiary or any other person to pay for those services.

"Covered" refers to services for which the law and the regulations authorize Medicare payment.

"Nominal charge provider" means a provider that furnishes services free of charge or at a nominal charge and is either a public provider, or another provider that (1) demonstrates to HCFA's satisfaction that a significant portion of its patients are low-income, and (2) requests that payment for its services be determined accordingly.

"Participating" refers to a hospital or other facility that meets the conditions of participation and has in effect a Medicare provider agreement.

"Qualified hospital" means a facility that—

(a) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled;

(b) Is not primarily engaged in providing skilled nursing care and related services for inpatients who require medical or nursing care;

(c) Provides 24-hour nursing service in accordance with Sec. 1861(e)(5) of the Act;

(d) If it is a U.S. hospital, is licensed, or approved as meeting the standards for licensing, by the State or local licensing agency; and

(e) If it is a foreign hospital, is licensed, or approved as meeting the standard for licensing, by the appropriate Canadian or Mexican licensing agency, and for purposes of furnishing non-emergency services to U.S. residents, is accredited by the Joint Commission on Accreditation of Hospitals (JCAH), or by a Canadian or Mexican program under standards that HCFA finds to be equivalent to those of the JCAH.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986]

§ 409.5 General description of benefits.

Hospital insurance (Part A of Medicare) helps pay for inpatient hospital services and posthospital SNF care. It also pays for home health services and hospice care. There are limitations on the number of days of care that Medicare can pay for and there are deductible and coinsurance amounts for which the beneficiary is responsible. For each type of service, certain conditions must be met as specified in the pertinent sections of this subpart and in Part 418 of this chapter regarding hospice care. The special conditions for inpatient hospital services furnished by a qualified U.S., Canadian, or Mexican hospital are set forth in Subparts G and H of Part 424 of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 53 FR 6648, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart B—Inpatient Hospital Care

§ 409.10 Included services.

(a) Subject to the conditions, limitations, and exceptions set forth in this subpart, the term "inpatient hospital services" means the following services furnished to an inpatient of a participating hospital or, in the case of emergency services or services in foreign hospitals, to an inpatient of a qualified hospital:

(1) Bed and board;

(2) Nursing services and other related services;

(3) Use of hospital facilities;

(4) Medical social services;

(5) Drugs, biologicals, supplies, appliances, and equipment;

(6) Certain other diagnostic or therapeutic services; and

(7) Medical or surgical services provided by certain interns or residents-in-training.

(b) "Inpatient hospital services" does not include SNF-type care or intermediate care facility (ICF)-type care furnished by a hospital that has a swing-bed approval.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.11 Bed and board.

(a) *Semiprivate and ward accommodations.* Except for applicable deductible and coinsurance amounts, Medicare Part A pays in full for bed and board and semiprivate (2 to 4 beds), or ward (5 or more beds) accommodations.

(b) *Private accommodations*—(1) *Conditions for payment in full.* Except for applicable deductible and coinsurance amounts, Medicare Part A pays in full for a private room if—

(i) The patient's condition requires him or her to be isolated;

(ii) The hospital has no semiprivate or ward accommodations; or

(iii) The hospital's semiprivate and ward accommodations are fully occupied by other patients, were so occupied at the time the patient was admitted to the hospital for treatment of a condition that required immediate inpatient hospital care, and have been so occupied during the interval.

(2) *Period of payment.* In the situations specified in paragraph (b)(1) (i) and (iii) of this section, Medicare pays for a private room until the patient's condition no longer requires isolation or until semiprivate or ward accommodations are available.

(3) *Conditions for patient's liability.* The hospital may charge the patient the difference between its customary charge for the private room and its most prevalent charge for a semiprivate room if—

(i) None of the conditions of paragraph (b)(1) of this section is met; and

(ii) The private room was requested by the patient or a member of the family, who, at the time of the request, was informed what the hospital's charge would be.

§ 409.12 Nursing and related services, medical social services; use of hospital facilities.

(a) Except as provided in paragraph (b) of this section, Medicare pays for nursing and related services, use of hospital facilities, and medical social services as inpatient hospital services only if those services are ordinarily furnished by the hospital for the care and treatment of inpatients.

(b) *Exception.* Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is a hospital employee at the time the services are furnished.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.13 Drugs and biologicals.

(a) Except as specified in paragraph (b) of this section, Medicare pays for drugs and biologicals as inpatient hospital services only if—

(1) They represent a cost to the hospital;

(2) They are ordinarily furnished by the hospital for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the hospital.

(b) *Exception.* Medicare pays for a limited supply of drugs for use outside the hospital if it is medically necessary to facilitate the beneficiary's departure from the hospital and required until he or she can obtain a continuing supply.

§ 409.14 Supplies, appliances, and equipment.

(a) Except as specified in paragraph (b) of this section, Medicare pays for supplies, appliances, and equipment as inpatient hospital services only if—

(1) They are ordinarily furnished by the hospital to inpatients; and

(2) They are furnished to inpatients for use in the hospital.

(b) *Exceptions.* Medicare pays for items to be used beyond the hospital stay if—

(1) The item is one that the beneficiary must continue to use after he or she leaves the hospital, for example, heart valves or a heart pacemaker, or

(2) The item is medically necessary to permit or facilitate the beneficiary's departure from the hospital and is required until the beneficiary can obtain a continuing supply. Tracheostomy or draining tubes are examples.

§ 409.15 Services furnished by an intern or a resident-in-training.

Medical or surgical services provided by an intern or a resident-in-training are included as "inpatient hospital services" if they are provided—

(a) By an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association, or the Bureau of Professional Education of the American Osteopathic Association;

(b) By an intern or a resident-in-training in the field of dentistry under a teaching program approved by the Council on Dental Education of the American Dental Association; or

(c) By an intern or a resident-in-training in the field of podiatry under a teaching program approved by the Council on Podiatry Education of the American Podiatry Association.

§ 409.16 Other diagnostic or therapeutic services.

Diagnostic or therapeutic services other than those provided for in §§ 409.12, 409.13, and 409.14 are considered as inpatient hospital services if—

(a) They are furnished by the hospital, or by others under arrangements made by the hospital;

(b) Billing for those services is through the hospital; and

(c) The services are of a kind ordinarily furnished to inpatients either by the hospital or under arrangements made by the hospital.

§ 409.18 Services related to kidney transplantations.

(a) *Kidney transplants.* Medicare pays for kidney transplantation surgery only if performed in a renal transplantation center approved under Subpart U of Part 405 of this chapter.

(b) *Services in connection with kidney donations.* Medicare pays for services related to the evaluation or preparation of a potential or actual donor, to the donation of the kidney, or to postoperative recovery services directly related to the kidney donation—

(1) If the kidney is intended for an individual who has ESRD and is entitled to Medicare benefits or can be expected to become so entitled within a reasonable time; and

(2) Regardless of whether the donor is entitled to Medicare.

§ 409.19 Services related to cardiac pacemakers and pacemaker leads.

(a) *Conditions.* Providers of services that request or receive payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads must submit information required by FDA under 21 CFR Part 805 for the pacemaker registry to HCFA in the form and manner set forth in the general instructions of the Medicare program.

(b) *Denial of payment.* Notwithstanding any other provisions of this chapter, payment will be denied to a provider of services with respect to the implantation, removal, or replacement of any permanent cardiac pacemaker or pacemaker lead when, and for so long as, HCFA determines in accordance with the procedures established in paragraph (c) of this section that the provider has failed to submit information required by FDA (under 21 CFR Part 805) for the pacemaker registry.

(c) *Notice of denial of payment.* (1) Whenever HCFA determines that a provider of services has failed to meet any of the requirements contained in paragraph (a) of this section or 21 CFR Part 805, HCFA will send written notice of its determination to the provider at least 45 days before the determination becomes effective.

(2) The notice will state the reasons for the determination and its effective date, and will grant the provider 45 days from the date of the notice to submit to HCFA information or evidence to demonstrate that HCFA's determination is in error. The notice will also inform the provider of its right to a hearing.

(3) Following the expiration of the 45-day notice period provided in paragraph (c)(1) of this section, HCFA's determination and notice constitute an "initial determination" and a "notice of initial determination" for purposes of the administrative and judicial appeal procedures specified in Part 498 of this chapter.

[52 FR 27764, July 23, 1987]

Subpart C—Posthospital SNF Care

§ 409.20 Coverage of services.

(a) *Included services.* Subject to the conditions and limitations set forth in this subpart and Subpart D of this part, "posthospital SNF care" means the following services furnished to an inpatient of a participating SNF or a hospital that has a swing-bed approval.

(1) Nursing care provided by or under the supervision of a registered professional nurse;

(2) Bed and board in connection with the furnishing of that nursing care;

(3) Physical, occupational, or speech therapy;

(4) Medical social services;

(5) Drugs, biologicals, supplies, appliances, and equipment;

(6) Certain medical services provided by an intern or resident-in-training;

(7) Certain other diagnostic or therapeutic services; and

(8) Other services that are necessary to the health of the patient and are generally provided by SNFs.

(b) *Excluded services*—(1) *Services that are not considered inpatient hospital services.* No service is included as posthospital SNF care if it would not be included as an inpatient hospital service under §§ 409.11 through 409.18.

(2) *Services not generally provided by SNFs.* Except as specifically listed in §§ 409.22 through 409.27, only those services generally provided by SNFs are considered as posthospital SNF care. For example, if an individual is furnished the use of an operating room by a SNF, that service is not included as "posthospital SNF care" because SNFs generally do not maintain operating rooms.

(c) *Terminology.* In §§ 409.22 through 409.36—

(1) The terms "SNF" and "swing-bed hospital" are used when the context applies to the particular facility.

(2) The term "facility" is used to mean both SNFs and swing-bed hospitals.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.22 Bed and board.

(a) *Semiprivate and ward accommodations.* Except for applicable deductible and coinsurance amounts Medicare Part A pays in full for semiprivate (2 to 4 beds), or ward (5 or more beds) accommodations.

(b) *Private accommodations*—(1) *Conditions for payment in full.* Except for applicable coinsurance amounts, Medicare pays in full for a private room if—

(i) The patient's condition requires him to be isolated;

(ii) The SNF has no semiprivate or ward accommodations; or

(iii) The SNF semiprivate and ward accommodations are fully occupied by other patients, were so occupied at the time the patient was admitted to the SNF for treatment of a condition that required immediate inpatient SNF care, and have been so occupied during the interval.

(2) *Period of payment.* In the situations specified in paragraph (b)(1) (i) and (iii) of this section. Medicare pays for a private room until the patient's condition no longer requires isolation or until semiprivate or ward accommodations are available.

(3) *Conditions for patient's liability.* The facility may charge the patient the difference between its customary charge for the private room furnished and its most prevalent charge for a semiprivate room if:

(i) None of the conditions of paragraph (b)(1) of this section is met, and

(ii) The private room was requested by the patient or a member of the family who, at the time of request was informed what the charge would be.

§ 409.23 Physical, occupational, and speech therapy.

Medicare pays for physical, occupational, or speech therapy as posthospital SNF care if—

(a) It is furnished by the facility or under arrangements made by the facility, and

(b) Billing for the therapy is by or through the facility.

§ 409.24 Drugs and biologicals.

(a) Except as specified in paragraph (b) of this section, Medicare pays for drugs and biologicals as posthospital SNF care only if—

(1) They represent a cost to the facility;

(2) They are ordinarily furnished by the facility for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the facility.

(b) *Exception.* Medicare pays for a limited supply of drugs for use outside the facility if it is medically necessary to facilitate the beneficiary's departure from the facility and required until he or she can obtain a continuing supply.

§ 409.25 Supplies, appliances, and equipment.

(a) Except as specified in paragraph (b) of this section, Medicare pays for supplies, appliances, and equipment as posthospital SNF care only if—

(1) They are ordinarily furnished by the facility to inpatients; and

(2) They are furnished to inpatients for use in the facility.

(b) *Exception.* Medicare pays for items to be used after the individual leaves the facility if—

(1) The item is one that the beneficiary must continue to use after leaving, such as a leg brace; or

(2) The item is necessary to permit or facilitate the beneficiary's departure from the facility and is required until he or she can obtain a continuing supply. Sterile dressings would be an example.

§ 409.26 Services furnished by an intern or a resident-in-training.

Medicare pays for medical services furnished by an intern or a resident-in-training as posthospital SNF care if—

(a) The intern or resident is in a participating hospital with which the SNF has in effect an agreement for the transfer of patients and exchange of medical records or in a hospital that has a swing-bed approval; and

(b) The intern or resident furnishes the services under a hospital teaching program approved in accordance with the provisions of § 409.15.

§ 409.27 Other diagnostic or therapeutic services.

Medicare pays for other diagnostic or therapeutic services as posthospital SNF care if they are provided by a participating hospital with which the SNF has in effect an agreement for the transfer of patients and exchange of clinical records, or by a hospital that has a swing-bed approval.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

Subpart D—Requirements for Coverage of Posthospital SNF Care

§ 409.30 Basic requirements.

Posthospital SNF care, including SNF-type care furnished in a hospital that has a swing-bed approval, is covered only if the beneficiary meets the requirements of this section and only for days when he or she needs and receives care of the level described in § 409.31.

(a) *Pre-admission requirements.* The beneficiary must—

(1) Have been hospitalized in a participating or qualified hospital, for medically necessary inpatient hospital care, for at least 3 consecutive calendar days, not counting the day of discharge; and

(2) Have been discharged from the hospital in or after the month he or she attained age 65, or in a month for which he or she was entitled to hospital insurance benefits on the basis of disability or end-stage renal disease, in accordance with Part 406 of this chapter.

(b) *Date of admission requirements.*[1] (1) Except as specified in paragraph (b)(2) of this section, the beneficiary must be in need of posthospital SNF care, be admitted to the facility, and receive the needed care within 30 calendar days after the date of discharge from a hospital.

(2) *Exception.* A beneficiary for whom posthospital SNF care would not be medically appropriate within 30 days after discharge from the hospital may be admitted at the time it would be medically appropriate to begin an active course of treatment.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41338, Nov. 14, 1986]

§ 409.31 Level of care requirement.

(a) *Definition.* As used in this section, "skilled nursing and skilled rehabilitation services" means services that:

(1) Are ordered by a physician;

(2) Require the skills of technical or professional personnel such as registered nurses, licensed practical (vocational) nurses, physical therapists, occupational therapists, and speech pathologists or audiologists; and

(3) Are furnished directly by, or under the supervision of, such personnel.

(b) *Specific conditions for meeting level of care requirements.* (1) The beneficiary must require skilled nursing or skilled rehabilitation services, or both, on a daily basis.

(2) Those services must be furnished for a condition—

(i) For which the beneficiary received inpatient hospital services; or

(ii) Which arose while the beneficiary was receiving care in a SNF or swing-bed hospital for a condition for which he or she received inpatient hospital services.

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[1] Before December 5, 1980, the law required that admission and receipt of care be within 14 days after discharge from the hospital and permitted admission up to 28 days after discharge if a SNF bed was not available in the geographic area in which the patient lived, or at the time it would be medically appropriate to begin an active course of treatment, if SNF care would not be medically appropriate within 14 days after discharge.

(3) The daily skilled services must be ones that, as a practical matter, can only be provided in a SNF, on an inpatient basis.

§ 409.32 Criteria for skilled services and the need for skilled services.

(a) The service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel.

(b) A condition that does not ordinarily require skilled services may require them because of special medical complications. Under those circumstances, a service that is usually nonskilled (such as those listed in § 409.33(d)) may be considered skilled because it must be performed or supervised by skilled nursing or rehabilitation personnel. For example, a plaster cast on a leg does not usually require skilled care. However, if the patient has a preexisting acute skin condition or needs traction, skilled personnel may be needed to adjust traction or watch for complications. In situations of this type, the complications, and the skilled services they require, must be documented by physicians' orders and nursing or therapy notes.

(c) The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities. For example, a terminal cancer patient may need some of the skilled services described in § 409.33.

§ 409.33 Examples of skilled nursing and rehabilitation services.

(a) *Services that could qualify as either skilled nursing or skilled rehabilitation services*—(1) *Overall management and evaluation of care plan.* The development, management, and evaluation of a patient care plan based on the physician's orders constitute skilled services when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs, promote recovery, and ensure medical safety. This would include the management of a plan involving only a variety of personal care services when, in light of the patient's condition, the aggregate of those services requires the involvement of technical or professional personnel. For example, an aged patient with a history of diabetes mellitus and angina pectoris who is recovering from an open reduction of a fracture of the neck of the femur requires, among other services, careful skin care, appropriate oral medications, a diabetic diet, an exercise program to preserve muscle tone and body condition, and observation to detect signs of deterioration in his or her condition or complications resulting from restricted, but increasing mobility. Although any of the required services could be performed by a properly instructed person, such a person would not have the ability to understand the relationship between the services and evaluate the ultimate effect of one service on the other. Since the nature of the patient's condition, age, and immobility create a high potential for serious complications, such an understanding is essential to ensure the patient's recovery and safety. Under these circumstances, the management of the plan of care would require the skills of a nurse even though the individual services are not skilled. Skilled planning and management activities are not always specifically identified in the patient's clinical record. Therefore, if the patient's overall condition would support a finding that recovery and safety can be assured only if the total care is planned, managed, and evaluated by technical or professional personnel, it would be appropriate to infer that skilled services are being provided.

(2) *Observation and assessment of the patient's changing condition.* Observation and assessment constitute skilled services when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification of treatment for additional medical procedures until his or her condition is stabilized. For example, a patient with congestive heart failure may require continuous close observation to detect signs of decompensation, abnormal

fluid balance, or adverse effects resulting from prescribed medication(s) which serve as indicators for adjusting therapeutic measures. Likewise, surgical patients transferred from a hospital to a skilled nursing facility while in the complicated, unstabilized postoperative period, e.g., after hip prosthesis or cataract surgery, may need continued close skilled monitoring for postoperative complications, and adverse reaction. Patients who, in addition to their physical problems, exhibit acute psychological symptoms such as depression, anxiety, or agitation, etc., may also require skilled observation and assessment by technical or professional personnel to assure their safety and/or the safety of others, i.e., to observe for indications of suicidal or hostile behavior. The need for services of this type must be documented by physicians' orders and/or nursing or therapy notes.

(3) *Patient education services.* Patient education services are skilled services if the use of technical or professional personnel is necessary to teach a patient self-maintenance. For example, a patient who has had a recent leg amputation needs skilled rehabilitation services provided by technical or professional personnel to provide gait training and to teach prosthesis care. Likewise, a patient newly diagnosed with diabetes requires instruction from technical or professional personnel to learn the self-administration of insulin or foot-care precautions, etc.

(b) *Services that qualify as skilled nursing services.* (1) Intravenous, intramuscular, or subcutaneous injections and hypodermoclysis or intravenous feeding;

(2) Levin tube and gastrostomy feedings;

(3) Nasopharyngeal and tracheostomy aspiration;

(4) Insertion and sterile irrigation and replacement of catheters;

(5) Application of dressings involving prescription medications and aseptic techniques;

(6) Treatment of extensive decubitus ulcers or other widespread skin disorder;

(7) Heat treatments which have been specifically ordered by a physician as part of active treatment and which require observation by nurses to adequately evaluate the patient's progress;

(8) Initial phases of a regimen involving administration of medical gases;

(9) Rehabilitation nursing procedures, including the related teaching and adaptive aspects of nursing, that are part of active treatment, e.g., the institution and supervision of bowel and bladder training programs.

(c) *Services which would qualify as skilled rehabilitation services.* (1) Ongoing assessment of rehabilitation needs and potential: Services concurrent with the management of a patient care plan, including tests and measurements of range of motion, strength, balance, coordination, endurance, functional ability, activities of daily living, perceptual deficits, speech and language or hearing disorders;

(2) Therapeutic exercises or activities: Therapeutic exercises or activities which, because of the type of exercises employed or the condition of the patient, must be performed by or under the supervision of a qualified physical therapist or occupational therapist to ensure the safety of the patient and the effectiveness of the treatment;

(3) Gait evaluation and training: Gait evaluation and training furnished to restore function in a patient whose ability to walk has been impaired by neurological, muscular, or skeletal abnormality;

(4) Range of motion exercises: Range of motion exercises which are part of the active treatment of a specific disease state which has resulted in a loss of, or restriction of, mobility (as evidenced by a therapist's notes showing the degree of motion lost and the degree to be restored);

(5) Maintenance therapy: Maintenance therapy, when the specialized knowledge and judgment of a qualified therapist is required to design and establish a maintenance program based on an initial evaluation and periodic reassessment of the patient's needs, and consistent with the patient's capacity and tolerance. For example, a patient with Parkinson's disease who has not been under a rehabilitation regimen may require the services of a

qualified therapist to determine what type of exercises will contribute the most to the maintenance of his present level of functioning.

(6) Ultrasound, short-wave, and microwave therapy treatment by a qualified physical therapist;

(7) Hot pack, hydrocollator, infrared treatments, paraffin baths, and whirlpool; Hot pack hydrocollator, infrared treatments, paraffin baths, and whirlpool in particular cases where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fractures, or other complications, and the skills, knowledge, and judgment of a qualified physical therapist are required; and

(8) Services of a speech pathologist or audiologist when necessary for the restoration of function in speech or hearing.

(d) *Personal care services.* Personal care services which do not require the skills of qualified technical or professional personnel are not skilled services except under the circumstances specified in § 409.32(b). Personal care services include, but are not limited to, the following:

(1) Administration of routine oral medications, eye drops, and ointments;

(2) General maintenance care of colostomy and ileostomy;

(3) Routine services to maintain satisfactory functioning of indwelling bladder catheters;

(4) Changes of dressings for noninfected postoperative or chronic conditions;

(5) Prophylacic and palliative skin care, including bathing and application of creams, or treatment of minor skin problems;

(6) Routine care of the incontinent patient, including use of diapers and protective sheets;

(7) General maintenance care in connection with a plaster cast;

(8) Routine care in connection with braces and similar devices;

(9) Use of heat as a palliative and comfort measure, such as whirlpool and hydrocollator;

(10) Routine administration of medical gases after a regimen of therapy has been established;

(11) Assistance in dressing, eating, and going to the toilet;

(12) Periodic turning and positioning in bed; and

(13) General supervision of exercises which have been taught to the patient; including the actual carrying out of maintenance programs, i.e., the performance of the repetitive exercises required to maintain function do not require the skills of a therapist and would not constitute skilled rehabilitation services (see paragraph (c) of this section). Similarly, repetitious exercises to improve gait, maintain strength, or endurance; passive exercises to maintain range of motion in paralyzed extremities, which are not related to a specific loss of function; and assistive walking do not constitute skilled rehabilitation services.

§ 409.34 Criteria for "daily basis".

(a) To meet the daily basis requirement specified in § 409.31(b)(1), the following frequency is required:

(1) Skilled nursing services or skilled rehabilitation services must be needed and provided 7 days a week; or

(2) As an exception, if skilled rehabilitation services are not available 7 days a week those services must be needed and provided at least 5 days a week.

(b) A break of one or two days in the furnishing of rehabilitation services will not preclude coverage if discharge would not be practical for the one or two days during which, for instance, the physician has suspended the therapy sessions because the patient exhibited extreme fatigue.

§ 409.35 Criteria for "practical matter".

(a) *General considerations.* In making a "practical matter" determination, as required by § 409.31(b)(3), consideration must be given to the patient's condition and to the availability and feasibility of using more economical alternative facilities and services. However, in making that determination, the availability of Medicare payment for those services may not be a factor. Example: The beneficiary can obtain daily physical therapy from a physical therapist in independent practice. However, Medicare pays only

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the appropriate portion (after deduction of applicable deductible and coinsurance amounts) of the first $500 of services furnished by such a practitioner in a year. This limitation on payment may not be a basis for finding that the needed care can only be provided in a SNF.

(b) *Examples of circumstances that meet practical matter criteria*—(1) *Beneficiary's condition.* Inpatient care would be required "as a practical matter" if transporting the beneficiary to and from the nearest facility that furnishes the required daily skilled services would be an excessive physical hardship.

(2) *Economy and efficiency.* Even if the beneficiary's condition does not preclude transportation, inpatient care might be more efficient and less costly if, for instance, the only alternative is daily transportation by ambulance.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.36 Effect of discharge from posthospital SNF care.

If a beneficiary is discharged from a facility after receiving posthospital SNF care, he or she is not entitled to additional services of this kind in the same benefit period unless—

(a) He or she is readmitted to the same or another facility within 30 calendar days following the day of discharge (or, before December 5, 1980, within 14 calendar days after discharge); or

(b) He or she is again hospitalized for at least 3 consecutive calendar days.

Subpart E—Home Health Services Under Hospital Insurance

§ 409.40 Included services.

Subject to the requirements and conditions set forth in § 409.42, "home health services" means the following items and services:

(a) Part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(b) Physical, occupational, or speech therapy;

(c) Medical social services provided under the direction of a physician;

(d) Part-time or intermittent services of a home health aide;

(e) Medical supplies (other than drugs and biologicals) and the use of durable medical equipment; and

(f) In the case of a home health agency (HHA) that is affiliated or under common control with a hospital, medical services provided by an intern or a resident-in-training of that hospital under a teaching program approved as provided in § 409.15.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41338, Nov. 14, 1986]

§ 409.41 Excluded services.

(a) *Services that are not considered inpatient hospital services.* No service is included as a home health service if it would not be included as an inpatient hospital service under Subpart B of this part.

(b) *Transportation.* Transportation required to take a homebound individual to a hospital, SNF, rehabilitation center or other place, to receive services that cannot be provided in the home, is not included as a home health service.

(c) *Housekeeping services.* The services of housekeepers or food service arrangements such as "meals-on-wheels" programs are not included as home health services.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.42 Requirements and conditions for home health services.

(a) *Basic rule.* The services specified in § 409.40 are covered by Medicare Part A only if the requirements of paragraphs (b) through (g) of this section are met.

(b) *Conditions the beneficiary must meet.* The beneficiary must be—

(1) Confined to the home or in an institution that is neither a hospital nor primarily engaged in providing skilled nursing or rehabilitation services;

(2) Under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine; and

(3) In need of intermittent skilled nursing care or physical or speech therapy or, effective July 1 through November 30, 1981, occupational therapy. After November 30, 1981, need for

occupational therapy is not a basis for initial qualification for home health services but does qualify a beneficiary for continued home health services even after he or she no longer needs intermittent skilled nursing care or physical or speech therapy.

(c) [Reserved] [1]

(d) *Plan of treatment requirements.*[2] The home health services must be furnished under a plan of treatment that is established and periodically reviewed by a doctor of medicine, osteopathy or, podiatric medicine. A doctor of podiatric medicine may establish a plan of treatment only if that is consistent with the home health agency's policy and with the functions he or she is authorized to perform under State law.

(e) *Where the services must be furnished.* (1) The home health services must be furnished—

(i) On a visiting basis in the individual's home; or

(ii) It it is necessary to use equipment that cannot readily be made available in the home, on an outpatient basis in a hospital, a SNF, or a rehabilitation center that meets State and local health and safety standards.

(2) If an individual is brought to a facility in accordance with paragraph (e)(1)(ii) of this section, other services that could be furnished in the home may be furnished in the facility at the same time.

(f) [Reserved] [3]

(g) *By whom the services must be furnished.* The home health services must be furnished by, or under arrangements made by a participating HHA.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

§ 409.43 Home health service visit.

(a) *Basic rule.* The furnishing of any of the home health services specified in § 409.40 by a particular health worker on a particular day or a particular time of the day constitutes a home health visit.

(b) *Specific examples.* (1) If both a physical therapist and a visiting nurse furnish services in the home on the same day, that constitutes two visits.

(2) If a beneficiary has dressings changed twice in the same day, that constitutes two visits.

(3) If a beneficiary is brought to the hospital for hydrotherapy, and while there also receives speech therapy, that constitutes two visits.

(4) If a nurse furnishes several services during a visit (for example, skilled nursing care and home health aide services), that constitutes only one visit.

[51 FR 41339, Nov. 14, 1986]

§ 409.44 Home health services under Medicare Part B.

Home health services are also covered under Medicare Part B, under the rules set forth in this Subpart E.

[51 FR 41339, Nov. 14, 1986]

§ 409.46 Coinsurance for durable medical equipment (DME) furnished as a home health service.

The coinsurance liability of the beneficiary or other person for DME furnished as a home health service is 20 percent of the customary (insofar as reasonable) charge for the services.

[51 FR 41339, Nov. 14, 1986]

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[1] Before July 1, 1981, Medicare Part A paid for home health services only if they were furnished to a beneficiary who—

- Had received inpatient care in a participating or qualified hospital or SNF; and
- Needed intermittent skilled nursing care, or physical or speech therapy for a codition for which he or she had received inpatient hospital or posthospital SNF care.

[2] Before January 1981, only a doctor of medicine or osteopathy could establish a plan for home health services. A plan of treatment established before July 1981 was acceptable for Medicare Part A payment only if it was established within 14 days after the individual's discharge from a hospital or SNF.

[3] Before July 1981, Medicare paid for not more than 100 home health visits, furnished—

- For Medicare Part A payment, during one year following the beneficiary's most recent discharge from a hospital or a SNF; and
- For Medicare Part B payment, within a calendar year.

Subpart F—Scope of Hospital Insurance Benefits

§ 409.60 Benefit periods.

(a) *When benefit periods begin.* The initial benefit period begins on the day the beneficiary receives inpatient hospital or SNF services for the first time after becoming entitled to hospital insurance. Thereafter, a new benefit period begins whenever the beneficiary receives inpatient hospital or SNF services after he or she has ended a benefit period as described in paragraph (b) of this section.

(b) *When benefit periods end.* (1) A benefit period ends when a beneficiary has, for at least 60 consecutive calendar days, not been an inpatient in any hospital that meets the requirements of section 1861(e)(1) of the Act or in any SNF that meets the requirements of section 1861(j)(1) or 1861(y) of the Act.

(2) For purposes of ending a benefit period, a beneficiary was an inpatient of a SNF if his or her care in the SNF met the skilled level of care requirements specified in § 409.31(b) (1) and (3).

(c) *Presumptions.* (1) For purposes of determining whether a beneficiary was an inpatient of a SNF under paragraph (b)(2) of this section—

(i) A beneficiary's care met the skilled level of care requirements if inpatient SNF claims were paid for those services under Medicare or Medicaid, unless:

(A) Such payments were made under § 405.330 or Medicaid administratively necessary days provisions which result in payment for care not meeting the skilled level of care requirements, or

(B) A Medicare denial and a Medicaid payment are made for the same period, in which case the presumption in paragraph (c)(2)(ii) of this section applies;

(ii) A beneficiary's care met the skilled level of care requirements if a SNF claim was paid under section 1879(e) of the Social Security Act;

(iii) A beneficiary's care did not meet the skilled level of care requirements if a SNF claim was paid for the services under § 405.330;

(iv) A beneficiary's care did not meet the skilled level of care requirements if a Medicaid SNF claim was denied on the grounds that the services were not at the skilled level of care (even if paid under applicable Medicaid administratively necessary days provisions which result in payment for care not meeting the skilled level of care requirements);

(2) For purposes of determining whether a beneficiary was an inpatient of a SNF under paragraph (b)(2) of this section a beneficiary's care in a SNF is presumed—

(i) To have met the skilled level of care requirements if a Medicaid or Medicare claim was denied on grounds other than that the services were not at the skilled level of care;

(ii) Not to have met the skilled level of care requirements if a Medicare SNF claim was denied on the grounds that the services were not at the skilled level of care and payment was not made under § 405.330; or

(iii) Not to have met the skilled level of care requirements if no Medicare or Medicaid claim was submitted by the SNF.

(3) If information upon which to base a presumption is not readily available, the intermediary may, at its discretion review the beneficiary's medical records to determine whether he or she was an inpatient of a SNF as set forth under paragraph (b)(2) of this section.

(4) When the intermediary makes a benefit period determination based upon paragraph (c)(1) of this section, the beneficiary may seek to reverse the benefit period determination by timely appealing the prior Medicare SNF claim determination under Part 405, Subpart G of this chapter, or the prior Medicaid SNF claim under Part 431, Subpart E of this chapter.

(5) When the intermediary makes a benefit period determination under paragraph (c)(2) of this section, the beneficiary will be notified of the basis for the determination, and of his or her right to present evidence to rebut the determination that the skilled level of care requirements specified in § 409.31 (b)(1) and (b)(3) were or were not met on reconsideration and appeal under 42 CFR, Part 405, Subpart G of this chapter.

(d) *Limitation on benefit period determinations.* When the intermediary

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considers the same prior SNF stay of a particular beneficiary in making benefit period determinations for more than one inpatient Medicare claim—

(1) Medicare will recognize only the initial level of care characterization for that prior SNF stay (or if appealed under 42 CFR Part 405, Subpart G of this chapter, the level of care determined under appeal); or

(2) If part of a prior SNF stay has one level of care characterization and another part has another level of care characterization, Medicare will recognize only the initial level of care characterization for a particular part of a prior SNF stay (or if appealed under 42 CFR Part 405, Subpart G of this chapter, the level of care determined under appeal).

(e) *Relation of benefit period to benefit limitations.* The limitations specified in §§ 409.61 and 409.64, and the deductible and coinsurance requirements set forth in Subpart G of this part apply for each benefit period. The limitations of § 409.63 apply only to the initial benefit period.

[52 FR 22645, June 15, 1987; 52 FR 28824, Aug. 4, 1987]

§ 409.61 General limitations on amount of benefits.

(a) *Inpatient hospital services.* (1) *Regular benefit days.* Up to 90 days are available in each benefit period, subject to the limitations on days for psychiatric hospital services set forth in §§ 409.62 and 409.63.

(i) For the first 60 days (referred to in this subpart as *full benefit days*), Medicare pays the hospital for all covered services furnished the beneficiary, except for a deductible which is the beneficiary's responsibility. (Section 409.82 specifies the requirements for the inpatient hospital deductible.)

(ii) For the next 30 days (referred to in this subpart as *coinsurance days*), Medicare pays for all covered services except for a daily coinsurance amount, which is the beneficiary's responsibility. (Section 409.83 specifies the inpatient hospital coinsurance amounts.)

(2) *Lifetime reserve days.* Each beneficiary has a non-renewable lifetime reserve of 60 days of inpatient hospital services that he may draw upon whenever he is hospitalized for more than 90 days in a benefit period. Upon exhaustion of the regular benefit days, the reserve days will be used unless the beneficiary elects not to use them, as provided in § 409.65. For lifetime reserve days, Medicare pays for all covered services except for a daily coinsurance amount that is the beneficiary's responsibility. (See § 409.83.)

(3) *Order of payment for inpatient hospital services.* Medicare pays for inpatient hospital services in the following order.

(i) The 60 full benefit days;

(ii) The 30 coinsurance days;

(iii) The remaining lifetime reserve days.

(b) *Posthospital SNF care.* Up to 100 days are available in each benefit period after discharge from a hospital. For the first 20 days, Medicare pays for all covered services. For the 21st through 100th day, Medicare pays for all covered services except for a daily coinsurance amount that is the beneficiary's responsibility. (Section 409.85 specifies the SNF coinsurance amounts.)

(c) *Renewal of inpatient benefits.* The beneficiary's full entitlement to the 90 inpatient hospital regular benefit days, and the 100 SNF benefit days, is renewed each time he or she begins a benefit period. However, once lifetime reserve days are used, they can never be renewed.

(d) *Home health services.* Medicare Part A pays for all covered home health services[4] with no deductible, and subject to the following limitations on payment for durable medical equipment (DME):

(1) For DME furnished by an HHA that is a nominal charge provider, Medicare Part A pays 80 percent of fair compensation.

(2) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part A pays the lesser of the following:

(i) 80 percent of the reasonable cost of the service.

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[4] Before July 1, 1981, Medicare Part A paid for not more than 100 home health visits during one year following the beneficiary's most recent discharge from a hospital or a SNF.

(ii) The reasonable cost of, or the customary charge for, the service, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41339, Nov. 14, 1986]

§ 409.62 Lifetime maximum on inpatient psychiatric care.

There is a lifetime maximum of 190 days on inpatient psychiatric hospital services available to any beneficiary. Therefore, once an individual receives benefits for 190 days of care in a psychiatric hospital, no further benefits of that type are available to that individual.

§ 409.63 Reduction of inpatient psychiatric benefit days available in the initial benefit period.

(a) *Reduction rule.* (1) If the individual was an inpatient in a psychiatric hospital on the first day of Medicare entitlement and for any of the 150 days immediately before that first day of entitlement, those days are subtracted from the 150 days (90 regular days plus 60 lifetime reserve days) which would otherwise be available in the initial benefit period for inpatient psychiatric services in a psychiatric or general hospital.

(2) Reduction is required only if the hospital was participating in Medicare as a psychiatric hospital on the individual's first day of entitlement.

(3) The reduction applies only to the beneficiary's first benefit period. For subsequent benefit periods, the 90 benefit days, plus any remaining lifetime reserve days, subject to the 190 day lifetime limit on psychiatric hospital care, are available.

(b) *Application to general hospital days.* (1) Days spent in a general hospital before entitlement are not subtracted under paragraph (a) of this section even if the stay was for diagnosis or treatment of mental illness.

(2) After entitlement, all psychiatric care days, whether in a general or a psychiatric hospital, are counted toward the number of days available in the initial benefit period.

(c) *Examples:* (1) The individual was an inpatient of a participating psychiatric hospital for 20 days before the first day of entitlement and remained there for another 6 months. Therefore, 130 days of benefits (150 minus 20) are payable. Payment could be made for: 60 full benefit days, 30 coinsurance days, and 40 lifetime reserve days.

(2) During the 150-day period preceding Medicare entitlement, an individual had been a patient of a general hospital for 60 days of inpatient psychiatric care and had spent 90 days in a psychiatric hospital, ending with the first day of entitlement. During the initial benefit period, the beneficiary spent 90 days in a general hospital and received psychiatric care there. The 60 days spent in the general hospital for psychiatric treatment before entitlement do not reduce the benefits available in the first benefit period. Only the 90 days spent in the psychiatric hospital before entitlement reduce such benefits, leaving a total of 60 available psychiatric days. However, after entitlement, the reduction applies not only to days spent in a psychiatric hospital, but also to days of psychiatric treatment in a general hospital. Thus, Medicare payment could be made only for 60 of the 90 days spent in the general hospital.

(3) An individual was admitted to a general hospital for a mental condition and, after 10 days, transferred to a participating psychiatric hospital. The individual remained in the psychiatric hospital for 78 days before becoming entitled to hospital insurance benefits and for 130 days after entitlement. The beneficiary was then transferred to a general hospital and received treatment of a medical condition for 20 days. The 10 days spent in the general hospital during the 150-day pre-entitlement period have no effect on the inpatient hospital benefit days available to the individual for psychiatric care in the first benefit period, even though the general hospital stay was for a mental condition. Only the 78 days spent in the psychiatric hospital during the pre-entitlement period are subtracted from the 150 benefit days. Accordingly, the individual has 72 days of psychiatric care (150 days less 78 days) available in the first benefit period. Benefits could be paid for the individual's hospitaliza-

tion during the first benefit period in the following manner. For the 130-day psychiatric hospital stay, 72 days (60 full benefit days and 12 coinsurance days), and for the general hospital stay, 20 days (18 coinsurance and 2 lifetime reserve days).

§ 409.64 Services that are counted toward allowable amounts.

(a) Except as provided in paragraph (b) of this section for lifetime reserve days, all covered inpatient days and home health visits are counted toward the allowable amounts specified in §§ 409.61 through 409.63 if—

(1) They are paid for by Medicare; or

(2) They would be paid for by Medicare if the following requirements had been met:

(i) A proper and timely request for payment had been filed; and

(ii) The hospital, SNF, or home health agency had submitted all necessary evidence, including physician certification of need for services when such certification was required; or

(3) They could not be paid for because the total payment due was equal to, or less than, the applicable deductible and coinsurance amounts.

(b) *Exception.* Even though the requirements of paragraph (a)(2) of this section are met, lifetime reserve days are not counted toward the allowable amounts if the beneficiary elected or is deemed to have elected not to use them as set forth in § 409.65.

§ 409.65 Lifetime reserve days.

(a) *Election not to use lifetime reserve days.* (1) Whenever a beneficiary has exhausted the 90 regular benefit days, the hospital may bill Medicare for lifetime reserve days unless the beneficiary elects not to use them or, in accordance with paragraph (b) of this section, is deemed to have elected not to use them.

(2) It may be advantageous to elect not to use lifetime reserve days if the beneficiary has private insurance coverage that begins after the first 90 inpatient days in a benefit period, or if the daily charge is only slightly higher than the lifetime reserve days coinsurance amount. In such cases, the beneficiary may want to save the lifetime reserve days for future care that may be more expensive.

(3) If the beneficiary elects not to use lifetime reserve days for a particular hospital stay, they are still available for a later stay. However, once the beneficiary uses lifetime reserve days, they can never be renewed.

(4) If the beneficiary elects not to use lifetime reserve days, the hospital may require him or her to pay for any services furnished after the regular days are exhausted.

(b) *Deemed election.* A beneficiary will be deemed to have elected not to use lifetime reserve days if the average daily charges for such days is equal to or less than the applicable coinsurance amount specified in § 409.83. A beneficiary would get no benefit from using the days under those circumstances.

(c) *Who may file an election.* An election not to use reserve days may be filed by—

(1) The beneficiary; or

(2) If the beneficiary is physically or mentally unable to act, by the beneficiary's legal representative. In addition, if some other payment source is available, such as private insurance, any person authorized under § 405.1664 of this chapter to execute a request for payment for the beneficiary may file the election.

(d) *Filing the election.* (1) The beneficiary's election not to use lifetime reserve days must be filed in writing with the hospital.

(2) The election may be filed at the time of admission to the hospital or at any time thereafter up to 90 days after the beneficiary's discharge.

(3) A retroactive election (i.e., one made after lifetime reserve days have been used because the regular days were exhausted), is not acceptable unless it is approved by the hospital.

(e) *Period covered by election*—(1) *General rule.* Except as provided in paragraph (e)(2) of this section, an election not to use lifetime reserve days may apply to an entire hospital stay or to a single period of consecutive days in a stay, but cannot apply to selected days in a stay. For example, a beneficiary may restrict the election to the period covered by private insurance but cannot use individual lifetime reserve days within that period. If an election not to use reserve days is effective after the first day on which reserve days are available, it must remain in effect until the end of the stay, unless it is revoked in accordance with § 409.66.

(2) *Exception.* A beneficiary election not to use lifetime reserve days for an inpatient hospital stay for which payment may be made under the prospective payment system (Part 412 of this chapter) is subject to the following rules:

(i) If the beneficiary has one or more regular benefit days (see § 409.61(a)(1) of this chapter) remaining in the benefit period upon entering the hospital, an election not to use lifetime reserve days will apply automatically to all days that are not outlier days. The beneficiary may also elect not to use lifetime reserve days for outlier days but this election must apply to all outlier days.

(ii) If the beneficiary has no regular benefit days (see § 409.61(a)(1) of this chapter) remaining in the benefit period upon entering the hospital, an election not to use lifetime reserve days must apply to the entire hospital stay.

[48 FR 12541, Mar. 25, 1983, as amended at 48 FR 39837, Sept. 1, 1983; 49 FR 323, Jan. 3, 1984]

§ 409.66 Revocation of election not to use lifetime reserve days.

(a) Except as provided in paragraph (c) of this section, a beneficiary (or anyone authorized to execute a request for payment, if the beneficiary is incapacitated) may revoke an election not to use lifetime reserve days during hospitalization or within 90 days after discharge.

(b) The revocation must be submitted to the hospital in writing and identify the stay or stays to which it applies.

(c) *Exceptions.* A revocation of an election not to use lifetime reserve days may not be filed—

(1) After the beneficiary dies; or

(2) After the hospital has filed a claim under the supplementary medical insurance program (Medicare Part B), for medical and other health services furnished to the beneficiary on the days in question.

§ 409.68 Guarantee of payment for inpatient hospital services furnished before notification of exhaustion of benefits.

(a) *Conditions for payment.* Payment may be made for inpatient hospital services furnished a beneficiary after he or she has exhausted the available benefit days if the following conditions are met:

(1) The services were furnished before HCFA or the intermediary notified the hospital that the beneficiary had exhausted the available benefit days and was not entitled to have payment made for those services.

(2) At the time the hospital furnished the services, it was unaware that the beneficiary had exhausted the available benefit days and could reasonably have assumed that he or she was entitled to have payment made for these services.

(3) Payment would be precluded solely because the beneficiary has no benefit days available for the particular hospital stay.

(4) The hospital claims reimbursement for the services and refunds any payments made for those services by the beneficiary or by another person on his or her behalf.

(b) *Limitations on payment.* (1) If all of the conditions in paragraph (a) of this section are met, Medicare payment may be made for the day of admission, and up to 6 weekdays thereafter, plus any intervening Saturdays, Sundays, and Federal holidays.

(2) Payment may not be made under this section for any day after the hospital is notified that the beneficiary has exhausted the available benefit days.

(c) *Recovery from the beneficiary.* Any payment made to a hospital under this section is considered an overpayment to the beneficiary and may be recovered from him or her under the provisions set forth elsewhere in this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

Subpart G—Hospital Insurance Deductibles and Coinsurance

§ 409.80 Inpatient deductible and coinsurance: General provisions.

(a) *What they are.* (1) The inpatient deductible and coinsurance amounts are portions of the cost of covered hospital or SNF services that Medicare does not pay.

(2) The hospital or SNF may charge these amounts to the beneficiary or someone on his or her behalf.

(b) *Changes in the inpatient deductible and coinsurance amounts.* (1) The law requires the Secretary to adjust the inpatient hospital deductible each year to reflect changes in the average cost of hospital care. In adjusting the deductible, the Secretary must use a formula specified in section 1813(b)(2) of the Act. Under that formula, the inpatient hospital deductible is increased each year by about the same percentage as the increase in the average Medicare daily hospital costs. The result of the deductible increase is that the beneficiary continues to pay about the same proportion of the hospital bill.

(2) Since the coinsurance amounts are, by statute, specific fractions of the deductible, they change when the deductible changes.

§ 409.82 Inpatient hospital deductible.

(a) *General provisions.* (1) The inpatient hospital deductible is a fixed amount chargeable to the beneficiary when he or she receives covered services in a hospital for the first time in a benefit period.

(2) Although the beneficiary may be hospitalized several times during a benefit period, the deductible is charged only once during that period. If the beneficiary begins more than one benefit period in the same year, a deductible is charged for each of those periods.

(3) For services furnished before January 1, 1982, the applicable deductible is the one in effect when the benefit period began.

(4) For services furnished after December 31, 1981, the applicable deductible is the one in effect during the calendar year in which the services were furnished.

(b) *Specific deductible amounts.* (1) The following chart specifies the deductible amounts for services furnished before January 1, 1982.

Benefit period began—	Amount of deductible
Before 1960	$40
In:	
1969	44
1970	52
1971	60
1972	68
1973	72
1974	84
1975	92
1976	104
1977	124
1978	144
1979	160
1980	180
1981	204

(2) The following chart specifies the deductible amounts for services furnished after December 31, 1981:

Services furnished in	Amount of deductible
1982	$260
1983	304

(c) *Exception.* If the total hospital charge is less than the amount shown under paragraph (b)(1) or (b)(2) of this section, the deductible is the amount of the charge.

§ 409.83 Inpatient hospital coinsurance.

(a) *General provisions.* (1) Inpatient hospital coinsurance is the amount chargeable to a beneficiary for each day after the first 60 days of inpatient hospital care in a benefit period.

(2) For each day from the 61st to the 90th day, the coinsurance amount is ¼ of the applicable deductible.

(3) For each day from the 91st to the 150th day (lifetime reserve days), the coinsurance amount is ½ of the applicable deductible.

(4) For coinsurance days before January 1, 1982, the coinsurance amount

is based on the deductible applicable for the calendar year in which the benefit period began. The coinsurance amounts do not change during a beneficiary's benefit period even though the coinsurance days may fall in a subsequent year for which a higher deductible amount has been determined.

(5) For coinsurance days after December 31, 1981, the coinsurance amount is based on the deductible applicable for the calendar year in which the services were furnished. For example, if an individual starts a benefit period by being admitted to a hospital in 1981 and remains in the hospital long enough to use coinsurance days in 1982, the coinsurance amount charged for those days is based on the 1982 inpatient hospital deductible.

(b) *Specific coinsurance amounts.* (1) The following chart specifies the daily hospital coinsurance amounts for services furnished before January 1, 1982:

Benefit period began—	61st to 90th day—	91st to 150th day—
Before 1969	$10	$20
In:		
1969	11	22
1970	13	26
1971	15	30
1972	17	34
1973	18	36
1974	21	42
1975	23	46
1976	26	52
1977	31	62
1978	36	72
1979	40	80
1980	45	90
1981	51	102

(2) The following chart specifies the daily hospital coinsurance amounts for services furnished after December 31, 1981:

Services furnished in	61st to 90th day	91st to 150th day
1982	$65	$130
1983	76	152

(c) *Exceptions.* (1) If the actual charge to the patient for the 61st through the 90th day of inpatient hospital services is less than the applicable coinsurance amount shown in paragraph (b)(1) or (b)(2) of this section, the coinsurance amount is the actual charge per day. (2) If the actual charge to the patient for the 91st through the 150th day (lifetime reserve days) is less than the applicable coinsurance amount shown in paragraph (b)(1) or (b)(2) of this section for those days, the beneficiary is deemed to have elected not to use the days because he or she would not benefit from using them.

§ 409.85 Skilled nursing facility (SNF) care coinsurance.

(a) *General provisions.* (1) SNF care coinsurance is the amount chargeable to a beneficiary after the first 20 days of SNF care in a benefit period.

(2) For each day from the 21st through the 100th day, the coinsurance is ⅛ of the applicable inpatient hospital deductible.

(3) For coinsurance days before January 1, 1982, the coinsurance amount is based on the deductible applicable for the year in which the benefit period began. The coinsurance amounts do not change during a beneficiary's benefit period even though the coinsurance days may fall in a subsequent year for which a higher deductible amount has been determined.

(4) For coinsurance days after December 31, 1981, the coinsurance amount is based on the deductible applicable for the calendar year in which the services were furnished.

(b) *Specific amounts of daily SNF coinsurance.* (1) The following chart specifies the daily coinsurance amounts for posthospital SNF care furnished before January 1, 1982:

Benefit period began—	Daily amount
Before 1969	$5.00
In:	
1969	5.50
1970	6.50
1971	7.50
1972	8.50
1973	9.00
1974	10.50
1975	11.50
1976	13.00

Benefit period began—	Daily amount
1977	15.50
1978	18.00
1979	20.00
1980	22.50
1981	25.50

(2) The following chart specifies the daily SNF coinsurance amounts for services furnished after December 31, 1981:

Services furnished in	Daily amount
1982	$32.50
1983	38.00

(c) *Exception.* If the actual charge to the patient is less than the applicable coinsurance amount shown under paragraph (b)(1) or (b)(2) of this section, the coinsurance is the actual charge per day.

§ 409.87 Blood deductible.

(a) *General provisions.* (1) As used in this section, packed red cells means the red blood cells that remain after plasma is separated from whole blood.

(2) A unit of packed red cells is treated as the equivalent of a unit of whole blood.

(3) Medicare does not pay for the first 3 units of whole blood or units of packed red cells that a beneficiary receives as an inpatient of a hospital or SNF during a benefit period. For example, if an individual receives 2 units of blood in a hospital and 3 units in a SNF during a single benefit period, the 2 units furnished in the hospital and the first unit furnished in the SNF would be the responsibility of the individual. Medicare would pay for the other 2 units furnished in the SNF.

(4) The deductible does not apply to other blood components such as platelets, fibrinogen, plasma, gamma globulin, and serum albumin, or to the cost of processing, storing, and administering blood.

(5) The blood deductible is in addition to the inpatient hospital deductible and daily coinsurance.

(6) There is also a separate Part B (supplementary medical insurance) blood deductible. Blood furnished under Part B of Medicare cannot be applied to satisfy the Part A (hospital insurance) blood deductible and blood furnished under Part A of Medicare cannot be applied to satisfy the Part B blood deductible.

(b) *Beneficiary's responsibility for the first 3 units of whole blood or packed red cells.* (1) *Basic rule.* Except as specified in paragraph (b)(2) of this section, the beneficiary is responsible for the first 3 units of whole blood or packed red cells. He or she has the option of paying the hospital's charges for the blood or packed red cells or arranging for it to be replaced.

(2) *Exception.* The beneficiary is not responsible for the first 3 units of whole blood or packed red cells if the provider obtained that blood or red cells at no charge other than a processing or service charge. In that case, the blood or red cells is deemed to have been replaced.

(c) *Provider's right to charge for the first 3 units of whole blood or packed red cells*—(1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, a provider may charge a beneficiary its customary charge for any of the first 3 units of whole blood or packed red cells.

(2) *Exception.* A provider may not charge the beneficiary for the first 3 units of whole blood or packed red cells in any of the following circumstances:

(i) The blood or packed red cells has been replaced.

(ii) The provider (or its blood supplier) receives, from an individual or a blood bank, a replacement offer that meets the criteria specified in paragraph (d) of this section. The provider is precluded from charging even if it or its blood supplier rejects the replacement offer.

(iii) The provider obtained the blood or packed red cells at no charge other than a processing or service charge and it is therefore deemed to have been replaced.

(d) *Criteria for replacement of blood.* A blood replacement offer made by a beneficiary, or an individual or a blood bank on behalf of a beneficiary, discharges the beneficiary's obligation to pay for deductible blood or packed red cells if the replacement blood meets the applicable criteria specified in Food and Drug Administration regulations under 21 CFR Part 640, i.e.—

(1) The replacement blood would not endanger the health of a recipient; and

(2) The prospective donor's health would not be endangered by making a blood donation.

§ 409.89 Exemption of kidney donors from deductible and coinsurance requirements.

The deductible and coinsurance requirements set forth in this subpart do not apply to any services furnished to an individual in connection with the donation of a kidney for transplant surgery.

Subpart H—Payment of Hospital Insurance Benefits

SOURCE: 53 FR 6633, Mar. 2, 1988, unless otherwise noted.

§ 409.100 To whom payment is made.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare pays hospital insurance benefits only to a participating provider.

(b) *Exceptions.* Medicare may pay hospital insurance benefits as follows:

(1) For emergency services furnished by a nonparticipating hospital, to the hospital or to the beneficiary, under the conditions prescribed in Subpart G of Part 424 of this chapter.

(2) For services furnished by a Canadian or Mexican hospital, to the hospital or to the beneficiary, under the conditions prescribed in Subpart H of Part 424 of this chapter.

§ 409.102 Amounts of payment.

(a) The amounts Medicare pays for hospital insurance benefits are generally determined in accordance with Part 412 or Part 413 of this chapter.

(b) Except as provided in §§ 409.61(d) and 409.89, hospital insurance benefits are subject to the deductible and coinsurance requirements set forth in Subpart G of this part.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

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410.175 Circumstances under which payment of benefits is prohibited.

Authority: Secs. 1102, 1832, 1833, 1835, 1861(r), (s) and (cc), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395k, 1395l, 1395n, 1395x(r), (s) and (cc), 1395hh, and 1395rr).

Source: 51 FR 41339, Nov. 14, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 410.1 Basis and scope.

(a) *Statutory basis.* Section 1832 of the Social Security Act establishes the scope of benefits provided under the Medicare Part B supplementary medical insurance (SMI) program. Sections 1833, 1835, and 1862 set forth the amounts of payment for SMI services, the conditions for payment, and the exclusions from coverage. Section 1861 defines the kinds of services that may be covered.

(b) *Scope of part.* This part sets forth the benefits available under Medicare Part B, the conditions for payment and the limitations on services, the percentage of incurred expenses that Medicare Part B pays, and the deductible and copayment amounts for which the beneficiary is responsible. (Exclusions applicable to these services are set forth in Subpart C of Part 405 of this chapter. General conditions for Medicare payment are set forth in Part 424 of this chapter.)

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.2 Definitions.

As used in this part—

"*Nominal charge provider*", means a provider that furnishes services free of charge or at a nominal charge, and is either a public provider, or another provider that (1) demonstrates to HCFA's satisfaction that a significant portion of its patients are low-income; and (2) requests that payment for its services be determined accordingly. "*Partcipating*" refers to a hospital, SNF, HHA, CORF, or hospice that has in effect a provider agreement to participate in Medicare, and "*nonparticipating*" refers to a hospital, SNF, HHA, CORF, or hospice that does not have in effect a provider agreement to participate in Medicare.

§ 410.3 Scope of benefits.

(a) *Covered services.* The SMI program helps pay for the following:

(1) Medical and other health services such as physicians' services, outpatient hospital services, diagnostic tests, outpatient physical therapy and speech pathology services, rural health clinic services and outpatient renal dialysis services.

(2) Services furnished by ambulatory surgical centers (ASCs), home health agencies (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs).

(3) Other medicial services, equipment, and supplies that are not covered under Medicare Part A hospital insurance.

(b) *Limitations on amount of payment.* (1) Medicare Part B does not pay the full reasonable costs or charges for all covered services. The beneficiary is responsible for an annual deductible and a blood deductible and, after the annual deductible has been satisfied, for coinsurance amounts specified for most of the services.

(2) Specific rules on payment are set forth in Subpart E of this part.

§ 410.5 Other applicable rules.

The following other rules of this chapter set forth additional policies and procedures applicable to three of the kinds of services covered under the SMI program:

(a) Part 405, Subpart U: End-Stage Renal Disease services.

(b) Part 405, Subpart X: Rural Health Clinic services.

(c) Part 416: Ambulatory Surgical Center services.

Subpart B—Medical and Other Health Services

§ 410.10 Medical and other health services: Includes services.

Subject to the conditions and limitations specified in § 410.12, "medical and other health services" includes the following services:

(a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies that are incident to physicians' services and are furnished to outpatients by or under arrangements made by a hospital.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital if the services are services that the hospital ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

[51 FR 41339, Nov. 14, 1986, as amended at 52 FR 27765, July 23, 1987]

§ 410.12 Medical and other health services: Basic conditions and limitations.

(a) *Basic conditions.* The medical and other health services specified in § 410.10 are covered by Medicare Part B only if they are not excluded under Subpart C of Part 405 of this chapter, and if they meet the following conditions:

(1) *When the services must be furnished.* The services must be furnished while the individual is in a period of entitlement. (The rules on entitlement are set forth in Part 406 of this chapter.)

(2) *By whom the services must be furnished.* The services must be furnished by a facility or other entity as specified in §§ 410.14 through 410.62.

(3) *Physician certification and recertification requirements.* If the services are subject to physician certification requirements, they must be certified as being medically necessary, and as meeting other applicable requirements, in accordance with Subpart B of Part 424 of this chapter.

(b) *Limitations on payment.* Payment for medical and other health services is subject to limitations on the amounts of payment as specified in §§ 410.152 and 410.155 and to the annual and blood deductibles as set forth in §§ 410.160 and 410.161.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.14 Special requirements for services furnished outside the United States.

Medicare Part B pays for physicians' services and ambulance services furnished outside the United States if the services meet the applicable conditions of § 410.12 and are furnished in connection with covered inpatient hospital services that meet the specific requirements and conditions set forth in Subpart H of Part 424 of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.20 Physicians' services.

(a) *Included services.* Medicare Part B pays for physicians' services, including diagnosis, therapy, surgery, consultations, and home, office, and institutional calls.

(b) *By whom services must be furnished.* Medicare Part B pays for the services specified in paragraph (a) of this section if they are furnished by one of the following professionals who is legally authorized to practice by the State in which he or she performs the functions or actions, and who is acting within the scope of his or her license.

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized in section 1101(a)(7) of the Act.

(2) A doctor of dental surgery or dental medicine.

(3) A doctor of podiatric medicine.

(4) A doctor of optometry.

(5) A chiropractor who meets the qualifications specified in § 410.22

(c) *Limitations on services.* The Services specified in paragraph (a) of this section may be covered under Medicare Part B if they are furnished within the limitations specified in §§ 410.22 through 410.25.

§ 410.22 Limitations on services of a chiropractor.

(a) *Qualifications for chiropractors.* (1) A chiropractor licensed or authorized to practice before July 1, 1974, and an individual who began studies in a chiropractic college before that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Graduated from a college of chiropractic approved by the State's chiropractic examiners after completing a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance and covering adequate courses of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing and adjusting; and

(iii) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(1)(ii) of this section.

(2) A chiropractor first licensed or authorized to practice after June 30, 1974, and an individual who begins studies in a chiropractic college after that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Satisfactorily completed 2 years of pre-chiropractic study at the college level;

(iii) Satisfactorily completed a 4-year course of 8 months each year offered by a college or school of chiropractic approved by the State's chiropractic examiners and including at least 4,000 hours in courses in anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, principles and practice of chiropractic, and clinical instruction in vertebral palpation, nerve tracing and adjusting, plus courses in the use and effect of X-ray and chiropractic analysis;

(iv) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(2)(iii) of this section; and

(v) Attained 21 years of age.

(b) *Limitations on services.* (1) Medicare Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation, if X-ray demonstrates that a subluxation exists and if the subluxation has resulted in a neuromusculoskeletal condition for which manipulation is appropriate treatment.

(2) Medicare Part B does not pay for X-rays or other diagnostic or therapeutic services furnished or ordered by a chiropractor.

§ 410.23 Limitations on services of an optometrist.

The services of optometrists are covered only if related to the condition of aphakia (absence of the natural crystalline lens of the eye, regardless of whether an intraocular lens has been implanted). The following are examples of examination services that may be covered when furnished by optometrists:

(a) Case history (the determination of changing visual performance as it relates to the condition of aphakia).

(b) External examination (the inspection with illumination and magnification of eyelids and surrounding areas of the eye).

(c) Ophthalmoscopy (the inspection with illumination and magnification of the internal structure of the eye).

(d) Biomicroscopy (the inspection of frontal tissues of the eye, using illumination and magnification). .

(e) Tonometry (the measurement of the internal pressure of the eye).

(f) Evaluation of visual fields (central and peripheral fields of vision).

(g) Evaluation of ocular motility (the determination of the ability of the eye to move efficiently).

(h) Evaluation of binocular function (the ability of the eye to obtain single, clear, two-eyed vision).

(i) Examination required to prescribe prosthetic lenses in connection with aphakia.

§ 410.24 Limitations on services of a doctor of dental surgery or dental medicine.

Medicare Part B pays for services furnished by a doctor of dental surgery or dental medicine within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.[6]

§ 410.25 Limitations on services of a podiatrist.

Medicare Part B pays for the services of a doctor of podiatric medicine, acting within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) Medicare Part B pays for services and supplies incident to a physician's professional services, including drugs and biologicals that cannot be self-administered, if the services or supplies are of the type that are commonly furnished in a physician's office or clinic, and are commonly furnished either without charge, or included in the physician's bill.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29.

§ 410.27 Outpatient hospital services and supplies incident to physicians' services: Conditions.

(a) Medicare Part B pays for hospital services and supplies furnished incident to physicians' services to outpatients, including drugs and biologicals that cannot be self-administered, if they are furnished—

(1) By or under arrangements made by a participating hospital; and

(2) As an integral though incidental part of a physician's services.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in Subpart G of Part 424 of this chapter.

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[6] For services furnished before July 1, 1981, Medicare Part B paid only for the following services of a doctor of dental surgery or dental medicine:

- Surgery on the jaw or any adjoining structure; and
- Reduction of a fracture of the jaw or other facial bone.

§ 410.28 Hospital diagnostic services furnished to outpatients: Conditions.

(a) Medicare Part B pays for hospital diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

(1) They are furnished by or under arrangements made by a participating hospital.

(2) They are ordinarily furnished by, or under arrangements made by, the hosptial to its outpatients for the purpose of diagnostic study.

(3) They would be covered as inpatient hospital services if furnished to an inpatient.

(4) If furnished under arrangements, they are furnished in the hospital or in other facilities operated by or under the supervision of the hospital or its organized medical staff.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29(b) and (c).

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in Subpart G of Part 424 of this chapter.

§ 410.29 Limitations on drugs and biologicals.

Medicare Part B does not pay for the following:

(a) Except as provided in § 410.28(a), any drug or biological that can be self-administered, whether furnished by a physician, a provider, or an entity other than a provider.

(b) Any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program, that there is a compelling justification of the drug product's medical need. (21 CFR 310.6 contains an explanation of the efficacy review program.)

(c) Any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (b) of this section.

§ 410.32 Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Diagnostic X-ray services*—(1) *Basic rule.* Except as specified in paragraph (a)(2) of this section, Medicare Part B pays for diagnostic X-ray services only if they are furnished under the immediate supervision of a physician who is a doctor of medicine, osteopathy, dental surgery, dental medicine, or podiatric medicine, or by a radiology department that meets the requirements for hospital radiology departments set forth in § 482.26 of this chapter.

(2) *Exception.* Medicare Part B pays for portable X-ray services, including services furnished in a place of residence used as the patient's home, if the services are furnished, under the general supervision of a physician, by a supplier that meets the conditions for coverage of portable X-ray services specified in Subpart N of Part 405 of this chapter.

(b) *Diagnostic laboratory tests.* Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:

(1) A participating hospital.

(2) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in Subpart G of Part 424 of this chapter and the laboratory requirements specified in § 405.1028 of this chapter.

(3) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine.

(4) A rural health clinic.

(5) An independent clinical laboratory, if it meets the conditions for coverage of services of independent laboratories specified in Subpart M of Part 405 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in Subpart G of Part 424 of this chapter.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

§ 410.34 X-ray therapy and other radiation therapy services: Scope.

Medicare Part B pays for X-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

§ 410.36 Medical supplies, appliances, and devices: Scope.

Medicare Part B pays for the following medical supplies, appliances and devices:

(a) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(b) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including replacement of those devices.

(c) Leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the individual's physical condition.

§ 410.38 Durable medical equipment: Scope and conditions.

(a) Medicare Part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) An institution that is used as a home may not be a hospital or a SNF as defined in sections 1861(e)(1) and 1861(j)(1) of the Act, respectively.

(c) Wheelchairs may include a power-operated vehicle that may be appropriately used as a wheelchair, but only if the vehicle—

(1) Is determined to be necessary on the basis of the individual's medical and physical condition; and

(2) Meets any safety requirements specified by HCFA.

§ 410.40 Ambulance services: Limitations.

(a) *Definitions.* As used in this section—

"*Ambulance*" means a vehicle that—

(1) Is specially designed for transporting the sick or injured;

(2) Contains a stretcher, linens, first aid supplies, oxygen equipment, and other lifesaving equipment required by State or local laws; and

(3) Is staffed with personnel trained to provide first aid treatment.

"*Appropriate hospital or SNF*" refers to a hospital or SNF that is capable of providing the required level and type of care for the patient's illness or injury and, in the case of a hospital, has available the type of physician or physician specialist needed to treat the patient's condition.

"*Hospital inpatient*" means a beneficiary who has been formally admitted to a hospital and has not been formally discharged.

"*Locality*" means the service area, surrounding a hospital or SNF, from which individuals normally come or are expected to come for hospital or SNF services.

"*Outside supplier*" means a hospital or a nonhospital treatment facility, such as a clinic, therapy center, or physician's office, where a hospital or SNF inpatient may be taken to receive medically necessary diagnostic or therapeutic services not available at the hospital or SNF where he or she is an inpatient.

(b) *Limits on coverage of ambulance transportation.* Medicare Part B pays for ambulance transportation only if—

(1) Other means of transportation would endanger the beneficiary's health;

(2) Medicare Part A payment is not available for the service; and

(3) In the case of a hospital inpatient—

(i) The transportation is furnished by, or under arrangements made by, the hospital; or

(ii) The transportation is furnished by an ambulance service with which the hospital does not have an arrangement (as defined in §409.3 of this chapter), and the hospital has a waiver (in accordance with § 489.23 of this chapter) under which Medicare Part B payment may be made to the ambulance service.

(c) *Limits on origins and destinations.* Medicare Part B pays for ambulance transportation of a beneficiary—

(1) To a hospital or SNF, from any point of origin;

(2) To his or her home, from a hospital or SNF; or

(3) Round trip from a hospital or a participating SNF to an outside supplier to obtain medically necessary diagnostic or therapeutic services not available at the hospital or SNF where the beneficiary is an inpatient.

(d) *Specific limits on coverage of ambulance transportation outside the United States.* In the case of services furnished outside the United States, Medicare Part B pays only for ambulance transportation to a foreign hospital and only in conjunction with the beneficiary's admission for medically necessary inpatient services as specified in Subpart H of Part 424 of this chapter.

(e) *Limitation on payments.* Medicare payments for ambulance services within the United States are limited to the amounts that would be paid for transportation—

(1) To an appropriate hospital or SNF in whose locality the beneficiary is located or, if the beneficiary is not in the locality of an appropriate hospital or SNF, to the nearest appropriate hospital or SNF;

(2) To the beneficiary's home from a hospital or SNF in whose locality the home is located, or from the nearest appropriate hospital or SNF; or

(3) Round trip to the nearest outside supplier capable of providing necessary diagnostic or therapeutic services not available at the hospital or SNF where the beneficiary is an inpatient.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.45 Rural health clinic services: Scope and conditions.

(a) Medicare Part B pays for the following rural health clinic services, if they are furnished in accordance with the requirements and conditions specified in Part 405, Subpart X, and Part 491 of this chapter:

(1) Physicians' services.

(2) Services and supplies furnished as an incident to physicians' professional services.

(3) Nurse practitioner and physician assistant services.

(4) Services and supplies furnished as an incident to nurse practitioners' or physician assistants' services.

(5) Visiting nurse services.

(b) Medicare pays for rural health clinic services when they are furnished at the clinic, at a hospital or other medical facility, or at the beneficiary's place of residence.

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

Medicare Part B pays for the following institutional dialysis services and supplies if they are furnished in approved ESRD facilities:

(a) All services, items, supplies, and equipment necessary to perform dialysis.

(b) Routine dialysis monitoring tests (i.e., hematocrit and clotting time) used by the facility to monitor the patients' fluids incident to each dialysis treatment, when performed by qualified staff of the facility under the direction of a physician, as provided in § 405.2163(b) of this chapter, even if the facility does not meet the conditions for coverage of services of independent laboratories in Subpart M of Part 405 of this chapter.

(c) Routine diagnostic tests.

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:

(1) Purchase or rental, installation, and maintenance of all dialysis equipment necessary for home dialysis, and reconditioning of this equipment. Dialysis equipment includes, but is not lim-

ited to, artificial kidney and automated peritoneal dialysis machines, and support equipment such as blood pumps, bubble detectors, and other alarm systems.

(2) Items and supplies required for dialysis, including (but not limited to) dialyzers, syringes and needles, forceps, scissors, scales, sphygmomanometer with cuff and stethoscope, alcohol wipes, sterile drapes, and rubber gloves.

(3) Home dialysis support services furnished by an approved ESRD facility, including periodic monitoring of the patient's home adaptation, emergency visits by qualified provider or facility personnel, any of the tests specified in paragraphs (b) through (d) of § 410.50, personnel costs associated with the installation and maintenance of dialysis equipment, testing and appropriate treatment of water, and ordering of supplies on an ongoing basis.

(b) Home dialysis support services specified in paragraph (a)(3) of this section must be furnished in accordance with a written treatment plan that is prepared and reviewed by a team consisting of the individual's physician and other qualified professionals. (Section 405.2137 of this chapter contains specific details.)

§ 410.55 Services related to kidney donations: Conditions.

Medicare Part B pays for medical and other health services covered under this subpart that are furnished in connection with a kidney donation—

(a) If the kidney is intended for an individual who has end-stage renal disease and is entitled to Medicare benefits; and

(b) Regardless of whether the donor is entitled to Medicare.

§ 410.57 Pneumococcal vaccine and its administration: Conditions.

Effective July 1, 1981, Medicare Part B pays for pneumococcal vaccine and its administration to a beneficiary, when reasonable and necessary for the prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.

§ 410.58 Additional services to HMO and CMP enrollees.

Services not usually covered under Medicare Part B may be covered as medical and other health services if they are furnished to an enrollee of an HMO or a CMP and the following conditions are met:

(a) The services are—

(1) Furnished by a physician assistant or nurse practitioner as defined in § 491.2 of this chapter, or are incident to services furnished by such a practitioner; or

(2) Furnished by a clinical psychologist as defined in § 417.416 of this chapter to an enrollee of an HMO or CMP that participates in Medicare under a risk-sharing contract, or are incident to those services.

(b) The services are services that would be covered under Medicare Part B if they were furnished by a physician or as incident to a physician's professional services.

§ 410.60 Outpatient physical therapy services: Conditions.

(a) *Basic rule.* Medicare Part B pays for outpatient physical therapy services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of Subpart B of Part 424 of this chapter.

(3) They are furnished—

(i) By a provider, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By or under the direct supervision of a physical therapist in independent practice who is licensed by the State in which he or she practices and who meets the qualifications specified in § 405.1702(d) of this chapter.

(b) *Outpatient physical therapy services to certain inpatients of a hospital or SNF.* Medicare Part B pays for outpatient physical therapy services furnished to an inpatient of a hospital or a SNF who requires them but who has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by physical therapists in independent practice*—(1) *Who is a physical therapist in independent practice.* A physical therapist in independent practice is one who—

(i) Engages in the practice of physical therapy on a regular basis;

(ii) Furnishes services on his or her own responsibility without the administrative and professional control of an employer;

(iii) Maintains, at his or her own expense, office space and the necessary equipment to provide an adequate program of physical therapy;

(iv) Furnishes services only in office space maintained at his or her expense, or in the patient's home; and

(v) Treats individuals who are his or her own patients and collects fees or other compensation for the services furnished.

(2) *Limitation on incurred expenses.* Not more than $500 of reasonable charges incurred in a calendar year are recognized as incurred expenses.[7]

(d) *Excluded services.* No service is included as an outpatient physical therapy service if it would not be included as an inpatient hospital service if furnished to an inpatient of a hospital.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.62 Outpatient speech pathology services: Conditions and exclusions.

(a) *Basic rule.* Medicare Part B pays for outpatient speech pathology services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine or osteopathy.

(2) They are furnished under a written plan of treatment that—

(i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech pathologist who will provide the services to the particular individual;

(ii) Is periodically reviewed by a physician; and

(iii) Meets the requirements of Subpart B of Part 424 of this chapter.

(3) They are furnished by a provider or by others under arrangements with, and under the supervision of, a provider.

(b) *Outpatient speech pathology services to certain inpatients of a hospital or SNF.* Medicare Part B pays for outpatient speech pathology services furnished to an inpatient of a hospital or SNF who requires them but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Excluded services.* No service is included as an outpatient speech pathology service if it would not be included as an inpatient hospital service if furnished to an inpatient of a hospital.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.64 Cardiac pacemakers and pacemaker leads.

(a) *Conditions.* Physicians and providers that request or receive payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads must submit to HCFA information required by FDA under 21 CFR Part 805 for the pacemaker registry in the form and manner set forth in the general instructions of the Medicare program.

(b) *Denial of payment.* Notwithstanding any other provisions of this chapter, HCFA will deny payment to a physician or provider who requests or receives payment from Medicare for the implantation, removal, or replacement of any cardiac pacemaker or pacemaker lead when, and for so long as, HCFA determines in accordance with the procedures established in paragraph (c) of this section that the physician or provider does not meet the reporting requirements in paragraph (a) of this section.

(c) *Notice of denial of payment.* (1) Whenever HCFA determines that a physician or provider has failed to meet any of the requirements contained in paragraph (a) of this section or 21 CFR Part 805, HCFA will send written notice of its determination to the physician or provider at least 45 days before the determination becomes effective.

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[7] Before 1982, not more than $100 was recognized as incurred expenses.

(2) The notice will state the reasons for the determination and its effective date, and will grant the physician or provider 45 days from the date of the notice to submit to HCFA information or evidence to demonstrate that HCFA's determination is in error. The notice will also inform the physician or provider of the right to a hearing.

(3) Following the expiration of the 45-day notice period provided in paragraph (c)(1) of this section, HCFA's determination and notice constitute an "initial determination" for purposes of the administrative and judicial appeal procedures specified in Part 498 of this chapter.

[52 FR 27765, July 23, 1987]

§ 410.66 Emergency outpatient services furnished by a nonparticipating hospital and services furnished in Mexico or Canada.

Conditions for payment of emergency outpatient services furnished by a nonparticipating U.S. hospital and for services furnished in Mexico or Canada are set forth in Subparts G and H of Part 424 of this chapter.

[53 FR 6634, Mar. 1, 1988; 53 FR 12945, April 20, 1988]

Subpart C—Home Health Services Under SMI

§ 410.80 Applicable rules.

Home health services furnished under Medicare Part B are subject to the rules set forth in Subpart E of Part 409 of this chapter.

Subpart D—Comprehensive Outpatient Rehabilitation Facility (CORF) Services

§ 410.100 Included services.

Subject to the conditions and limitations set forth in §§ 410.102 and 410.105, CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in § 485.70 of this chapter.

(a) *Physicians' services.* The following services of the facility physician constitute CORF services: consultation with and medical supervision of non-physician staff, establishment and review of the plan of treatment, and other medical and facility administration activities. Those services are reimbursed on a reasonable cost basis under Part 413 of this chapter. Diagnostic and therapeutic services furnished to an individual patient are not CORF physician's services. If covered, payment for these services would be made by the carrier on a reasonable charge basis subject to the provisions of Subpart E of Part 405 of this chapter.

(b) *Physical therapy services.* (1) These services include—

(i) Testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular and respiratory systems; and.

(ii) Assessment and treatment related to dysfunction caused by illness or injury, and aimed at preventing or reducing disability or pain and restoring lost function.

(2) The establishment of a maintenance therapy program for an individual whose restoration potential has been reached is a physical therapy service; however, maintenance therapy itself is not covered as part of these services.

(c) *Occupational therapy services.* These services include—

(1) Teaching of compensatory techniques to permit an individual with a physical impairment or limitation to engage in daily activities.

(2) Evaluation of an individual's level of independent functioning.

(3) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; and

(4) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(d) *Speech-language pathology services.* These are services for the diagnosis and treatment of speech and language disorders that create difficulties in communication.

(e) *Respiratory therapy services.* (1) These are services for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies or abnormalities of cardiopulmonary function.

(2) These services include—

(i) Application of techniques for support of oxygenation and ventilation of the patient and for pulmonary rehabilitation.

(ii) Therapeutic use and monitoring of gases, mists, and aerosols and related equipment;

(iii) Bronchial hygiene therapy;

(iv) Pulmonary rehabilitation techniques such as exercise conditioning, breathing retraining and patient education in the management of respiratory problems.

(v) Diagnostic tests to be evaluated by a physician, such as pulmonary function tests, spirometry and blood gas analysis; and

(vi) Periodic assessment of chronically ill patients and their need for respiratory therapy.

(f) *Prosthetic device services.* These services include—

(1) Prosthetic devices (excluding dental devices and renal dialysis machines), that replace all or part of an internal body organ or external body member (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning external body member or internal body organ; and

(2) Services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct the patient in its use.

(g) *Orthotic device services.* These services include—

(1) Orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning; and

(2) Services necessary to design the device, select the materials and components, measure, fit, and align the device, and instruct the patient in its use.

(h) *Social services.* These services include—

(1) Assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, and adjustment to care furnished by the facility;

(2) Casework services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and

(3) Assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care.

(i) *Psychological services.* These services include—

(1) Assessment, diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation;

(2) Psychological evaluations of the individual's response to and rate of progress under the treatment plan; and

(3) Assessment of those aspects of an individual's family and home situation that affect the individual's rehabilitation treatment.

(j) *Nursing care services.* These services include nursing services specified in the plan of treatment and any other nursing services necessary for the attainment of the rehabilitation goals.

(k) *Drugs and biologicals.* These are drugs and biologicals that are—

(1) Prescribed by a physician and administered by or under the supervision of a physician or a registered professional nurse; and

(2) Not excluded from Medicare Part B payment for reasons specified in § 410.29.

(l) *Supplies, appliances, and equipment.* These include—

(1) Non-reusable supplies such as oxygen and bandages;

(2) Medical equipment and appliances; and

(3) Durable medical equipment of the type specified in § 410.38, (except renal dialysis systems) for use outside the CORF, whether purchased or rented.

(m) *Home environment evaluation.* This is a single home visit to evaluate the potential impact of the home situation on the rehabilitation goals.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

§ 410.102 Excluded services.

None of the services specified in § 410.100 is covered as a CORF service if the service—

(a) Would not be covered as an inpatient hospital service if furnished to a hospital inpatient;

(b) Is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. An example would be services furnished as part of a maintenance program involving repetitive activities that do not require the skilled services of nurses or therapists.

§ 410.105 Requirements for coverage of CORF services.

Services specified in § 410.100 and not excluded under § 410.102 are covered as CORF services if the following requirements are met:

(a) *Referral and medical history.* The services must be furnished to an individual who is referred by a physician who certifies that the individual needs skilled rehabilitation services, and makes the following information available to the CORF before or at the time treatment is begun:

(1) The individual's significant medical history.

(2) Current medical findings.

(3) Diagnosis(es) and contraindications to any treatment modality.

(4) Rehabilitation goals, if determined.

(b) *When and where services are furnished.* (1) All services must be furnished while the individual is under the care of a physician; and

(2) Except for the home evaluation visit described in § 410.100(m), the services must be furnished onsite at a participating CORF. (The conditions for CORF participation in Medicare are set forth in Part 485, (Subpart B, of this chapter.)

(c) *Plan of treatment.* (1) The services must be furnished under a written plan of treatment that—

(i) Is established and signed by a physician before treatment is begun; and

(ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals.

(2) The plan must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing the services.

(3) The reviewing physician must certify or recertify that the plan is being followed, the patient is making progress in attaining the rehabilitation goals, and the treatment is having no harmful effects on the patient.

Subpart E—Payment of SMI Benefits

§ 410.150 To whom payment is made.

(a) *General rules.* (1) Any SMI enrollee is, subject to the conditions, limitations, and exclusions set forth in this Part and in Parts 405, 416 and 424 of this chapter, entitled to have payment made as specified in paragraph (b) of this section.

(2) The services specified in paragraphs (b)(5) through (b)(11) of this section must be furnished by a facility that has in effect a provider agreement or other appropriate agreement to participate in Medicare.

(b) *Specific rules.* Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

(1) To the individual, or to a physician or other supplier on the individual's behalf, for medical and other health services furnished by the physician or other supplier.

(2) To a nonparticipating hospital on the individual's behalf for emergency outpatient services furnished by the hospital, in accordance with Subpart G of Part 424 of this chapter.

(3) To the individual, for emergency outpatient services furnished by a nonparticipating hospital, in accordance with § 424.53 of this chapter.

(4) To the individual, for physicians' services and ambulance services furnished outside the United States in accordance with § 424.53 of this chapter.

(5) To a provider on the individual's behalf for medical and other health services furnished by the provider (or by others under arrangements made with them by the provider).

(6) To a home health agency on the individual's behalf for home health services furnished by the home health agency.

(7) To a clinic, rehabilitation agency, or public health agency on the individual's behalf for outpatient physical therapy or speech pathology services furnished by the clinic or agency (or by others under arrangements made with them by the clinic or agency).

(8) To a rural health clinic on the individual's behalf for rural health clinic services furnished by the rural health clinic.

(9) To an ambulatory surgical center (ASC) on the individual's behalf for covered ambulatory surgical center facility services that are furnished in connection with surgical procedures performed in an ASC, as provided in Part 416 of this chapter.

(10) To a comprehensive outpatient rehabilitation facility (CORF) on the individual's behalf for comprehensive outpatient rehabilitation facility services furnished by the CORF.

(11) To a renal dialysis facility, on the individual's behalf, for institutional or home dialysis services, supplies, and equipment furnished by the facility.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.152 Amounts of payment.

(a) *General provisions*—(1) *Exclusion from incurred expenses.* As used in this section, "incurred expenses" are expenses incurred by an individual, during his or her coverage period, for covered Part B services, excluding the following:

(i) Expenses incurred for services for which the beneficiary is entitled to have payment made under Medicare Part A or would be so entitled except for the application of the Part A deductible and coinsurance requirements.

(ii) Expenses incurred in meeting the Part B blood deductible (§ 410.161).

(iii) In the case of services reimbursable under a formula that takes into account reasonable charges, reasonable costs, customary charges, customary (insofar as reasonable) charges, fair compensation, a per-treatment prospective payment rate, or a standard overhead amount, or any combination of two or more of these factors, expenses in excess of any factor taken into account under that formula.

(iv) In the case of physician and CORF services, for the treatment of a mental, psychoneurotic, or personality disorder, furnished to an individual who is not an inpatient of a hospital, expenses for a calendar year in excess of the lesser of $312.50 or 62 percent of the reasonable charge.

(v) In the case of expenses incurred for outpatient physical therapy furnished by therapists in independent practice, expenses in excess of $500 in reasonable charges incurred in a calendar year.

(2) *Other applicable provisions.* Medicare Part B pays for incurred expenses the amounts specified in paragraphs (b) through (h) of this section, subject to the following:

(i) The principles and procedures for determining reasonable costs and reasonable charges and the conditions for Medicare payment, as set forth in Parts 405 (Subparts E and X), 413, and 424 of this chapter.

(ii) The Part B annual deductible (§ 410.160).

(iii) The special rules for payment to health maintenance organizations (HMOs), health care prepayment plans (HCPPs), and competitive medical plans (CMPs) that are set forth in Part 417 of this chapter. (A prepayment organization that does not qualify as an HMO CMP, or HCPP is paid in accordance with § 410.172)

(b) *Basic rules for payment.* Except as specified in paragraphs (c) through (h) of this section, Medicare Part B pays the following amounts:

(1) For services furnished by, or under arrangements made by, a provider other than a nominal charge provider, whichever of the following is less:

(i) 80 percent of the reasonable cost of the services.

(ii) The reasonable cost of, or the customary charges for, the services, whichever is less, minus 20 percent of the customary (insofar as reasonable) charges for the services.

(2) For services furnished by, or under arrangements made by, a nomi-

nal charge provider, 80 percent of fair compensation.

(3) For emergency outpatient hospital services furnished by a nonparticipating hospital that is eligible to receive payment for those services under Subpart G of Part 424 of this chapter, the amount specified in paragraph (b)(1) of this section.

(4) For services furnished by a person or an entity other than those specified in paragraphs (b)(1), (b)(2) and (b)(3) of this section, 80 percent of the reasonable charges for the services.

(c) *Amount of payment: Home health services other than durable medical equipment (DME).* For home health services other than DME furnished by, or under arrangements made by, a participating HHA, Medicare Part B pays the following amounts:

(1) For services furnished by an HHA that is a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by an HHA that is not a nominal charge provider, the lesser of the reasonable cost of the services and the customary charges for the services.

(d) *Amount of payment: DME furnished as a home health service.*

(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section—

(i) For DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 80 percent of fair compensation.

(ii) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays the lesser of the following:

(A) 80 percent of the reasonable cost of the service.

(B) The reasonable cost of, or the customary charge for, the service, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

(2) *Exception.* If the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for new equipment—

(i) For used DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 100 percent of fair compensation.

(ii) For used DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays 100 percent of the reasonable cost of, or the customary charge for, the services, whichever is less.

(e) *Amount of payment: Renal dialysis services, supplies, and equipment.* Effective for services furnished on or after August 1, 1983, Medicare Part B pays for the institutional dialysis services specified in § 409.250 and the home dialysis services, supplies, and equipment specified in § 409.252, as follows:

(1) Except as provided in paragraph (d)(2) of this section, 80 percent of the per treatment prospective reimbursement rate established under § 413.170 of this chapter, for outpatient maintenance dialysis furnished by ESRD facilities approved in accordance with Subpart U of Part 405 of this chapter.

(2) *Exception.* If a home dialysis patient elects to obtain home dialysis supplies or equipment (or both) from a party other than an approved ESRD facility, payment is in accordance with paragraph (b)(4) of this section.

(f) *Amount of payment: Rural health clinic services.* Medicare Part B pays, for services by a participating independent rural health clinic, 80 percent of the costs determined under Subpart X of Part 405 of this chapter, to the extent those costs are reasonable and related to the cost of furnishing rural health clinic services or reasonable on the basis of other tests specified by HCFA.

(g) *Amount of payment: Used durable medical equipment furnished by other than an HHA.* Medicare Part B pays the following amounts for used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment:

(1) For used DME furnished by, or under arrangements made by, a nominal charge provider, 100 percent of fair compensation.

(2) For used DME furnished by or under arrangements made by a provider that is not a nominal charge provider, 100 percent of the reasonable cost of the service or the customary charge for the service, whichever is less.

(3) For used DME furnished by other than a provider, 100 percent of the reasonable charge.

(h) *Amount of payment: Pneumococcal vaccine.* Medicare Part B pays of pneumococcal vaccine and its administration as follows:

(1) For services furnished by a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by a provider that is not a nominal charge provider, the reasonable cost of the services or the customary charge for the service, whichever is less.

(3) For services furnished by other than a provider or a rural health clinic, 100 percent of the reasonable charge.

(4) For services furnished by a rural health clinic, reimbursement is in accordance with paragraph (f) of this section.

(i) *Amount of payment: Ambulatory surgical services*—(1) *Physician services.* Effective for services furnished after September 6, 1982, Medicare Part B pays 100 percent of the reasonable charges (or 100 percent of the reasonable cost in the case of an HMO reimbursed in accordance with Part 416 of this chapter) for physician services (including all pre-operative and post-operative services) furnished in connection with surgical procedures specified in Part 416 of this chapter, if the following conditions are met:

(i) The procedures are performed in a participating ambulatory surgical center (ASC), on an outpatient basis in a participating hospital, or in a participating hospital-affiliated ASC.

(ii) The physician accepts assignment of the right to receive payment for the services (in accordance with § 424.55 or § 424.56 of this chapter) or qualifies to receive payment for the services (under § 424.64 of this chapter) when the beneficiary dies without assigning the right to payment. Under Subpart F of Part 424 of this chapter, a physician may authorize an employer, facility, or organization to accept assignment or to claim payment on his or her behalf, in accordance with § 424.55 or § 424.56 and § 424.64 of this chapter.

If the conditions of this paragraph (i) are not met, Medicare Part B pays 80 percent of reasonable charges for the services.

(2) *Amount of payment: ASC facility services.* Effective for services furnished after September 6, 1982, Medicare Part B pays a standard overhead amount, as specified in § 416.120(c) of this chapter, for ASC facility services that are furnished in connection with surgical procedures specified in § 416.65 of this chapter.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.155 Psychiatric services limitations: Expenses incurred for physician services and CORF services.

(a) *Definitions.* As used in this section, unless the context indicates otherwise, "*Mental, psychoneurotic, or personality disorder*" means the specific psychiatric conditions described in the American Psychiatric Association's Diagnostic and Statistical Manual—Mental Disorders. "*Hospital*" means any hospital that is primarily engaged in providing, by or under the supervision of physicians, diagnostic and therapeutic services for the medical diagnosis, treatment, and care of injured, disabled or sick persons, or rehabilitation services for the rehabilitation of injured, disabled or sick persons; or psychiatric services for the diagnosis and treatment of mentally ill persons; and medical services for the diagnosis and treatment of tuberculosis.

(b) *Services subject to limitation.* The psychiatric services limitation applies to physician services and CORF services (furnished by physicians or nonphysicians) for the treatment of a mental, psychoneurotic, or personality disorder, when the services are furnished to an individual who is not an inpatient in a hospital.

(c) *Limitation.* Of the expenses incurred during any calendar year for services specified in paragraph (b) of this section, only $312.50 or 62½ percent of the expenses (whichever is less) will be considered reimbursable under Medicare Part B, subject to the amount of payment and deductible provisions set forth in §§ 410.152 and 410.160.

(d) *Example.*

As a private patient, Mr. X's only medical expenses during the calendar year 1982 amounted to $750 for physicians' services in connection with the treatment of a mental disorder which did not require inpatient hospitalization. The statutory limit for any calendar year on the amount of these expenses that is covered under this Subpart B is $312.50 ($312.50 being lesser in amount than 62½ percent of $750). Mr. X is required to meet the first $75 as a deductible, and 20 percent of the balance. The remaining 80 percent is payable under this Subpart B.

Total covered expenses	Mr. X's payment	Payment under subpart B
$312.50	[2] $437.50	
-75.00 [1]	[1] 75.00	
237.50	[3] 47.50	[4] 190.00

[1] Deductible, as described in § 409.360.
[2] In excess of $312.50.
[3] 20 percent of total covered expenses less deductible.
[4] 80 percent of total covered expenses less deductible.

If Mr. X had incurred $350 of the above expenses while an inpatient of an institution (see paragraph (b) of this section), and the remaining $400 while not an inpatient of an institution, payment would be computed as follows:

Total covered expenses	Mr. X's payment	Payment under subpart B
$250 [1]	[2] $150	
+350 [3]		
600	[4] 75	
-75		
525	[5] 105	[6] 420

[1] 62½ percent of $400.
[2] In excess of 62½ percent of $400.
[3] 100 percent of expenses incurred while an inpatient.
[4] Deductible.
[5] 20 percent of total covered expenses less deductible.
[6] 80 percent of total covered expenses less deductible.

§ 410.160 Part B annual deductible.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, incurred expenses (as defined in § 410.152) are subject to, and count toward meeting the annual deductible.

(b) *Exceptions.* The following incurred expenses are not subject to the Part B annual deductible and do not count toward meeting that deductible:

(1) Home health services.[8]

(2) Pneumococcal vaccines and their administration.

(3) Physician services furnished in connection with ambulatory surgery if those services meet the requirements of § 410.152(i)(1) for payment of 100 percent of reasonable charges.

(4) ASC facility services.

(c) *Application of the Part B annual deductible.* (1) Before payment is made under § 410.152, an individual's incurred expenses for the calendar year are reduced by the Part B annual deductible.

(2) The Part B annual deductible is applied to incurred expenses in the order in which claims for those expenses are processed by the Medicare program.

(3) Only one Part B annual deductible may be imposed for any calendar year and it may be met by any combination of expenses incurred in that year.

(d) *Special rule for services reimbursable on a formula basis.* (1) In applying the formula that takes into account reasonable costs, customary charges, and customary (insofar as reasonable) charges, and is used to determine payment for services furnished by a provider that is not a nominal charge provider, the Medicare intermediary takes the following steps:

(i) Reduces the customary charges for the services by an amount equal to any unmet portion of the deductible for the calendar year, in accordance with paragraph (b) of this section. (The amount of this reduction is considered to be the amount of the deductible that is met on the basis of the services to which it is applied.)

(ii) Determines 20 percent of any remaining portion of the customary (insofar as reasonable) charge.

(iii) Determines the lesser of the reasonable cost of the services and the customary charges for the services.

(iv) Reduces the amount determined under paragraph (c)(1)(iii) of this section by the sum of the reduction made under paragraph (c)(1)(i) of this section and the amount determined under parargaph (c)(1)(ii) of this section.

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[8] Before July 1981, home health services were subject to the Part B annual deductible.

(v) Reduces the reasonable cost of the services by the amount of the reduction made under paragraph (c)(1)(i) of this section and multiplies the result by 80 percent.

(2) In accordance with § 410.152(b)(1), the amount payable is the amount determined under paragraph (c)(1)(iv) of this section, or the amount determined under paragraph (c)(1)(v) of this section, whichever is less.

(e) *Special rule for services of an independent rural health clinic.* Application of the Part B annual deductible to rural health clinic services is in accordance with § 405.2425(b)(2) of this chapter.

(f) *Amount of the Part B annual deductible.* (1) Beginning with expenses for services furnished during calendar year 1982, the Part B annual deductible is $75.

(2) From 1973 through 1981, the deductible was $60.

(3) From 1966 through 1972, the deductible was $50.

(g) *Carryover of Part B annual deductible.* For calendar years before 1982, the Part B annual deductible was reduced by the amount of expenses incurred during the last quarter of the preceding year that was applied to meet the deductible for that preceding year. *Example:* If $20 of expenses incurred in November 1980 was used to meet the 1980 deductible, the 1981 deductible was reduced to $40 ($60-$20).

(h) *Examples of application of the annual deductible.* (1) Mr. A submitted claims for the following expenses incurred during 1982: $20 for services furnished in March by physician X; $30 for services furnished in April by physician Y; $50 for services furnished in June by physician Z, for a total of $100. The carrier determined that the charges as submitted were the reasonable charges. The first $75 of expenses for which claims were processed is applied to meet the $75 deductible for that year. Medicare Part B pays 80 percent of the remaining $25, or $20.

(2) Mr. B submitted a claim that included a $25 charge by a doctor for an examination to prescribe a hearing aid and an $80 charge for office surgery. This was the first claim relating to Mr. B's medical expenses processed in the calendar year. The carrier disallowed the $25 charge because the type of examination is not covered by Medicare. The carrier reduced the $80 surgery charge to a reasonable charge of $40. Only the $40 reasonable charge for covered services will count toward meeting Mr. B's deductible. Since the remainder of the surgery charge constitutes and excess over the reasonable charge, it cannot be applied to satisfy Mr. B's deductible.

(3) Mr. C became entitled to Medicare Part B benefits on July 1, 1982. He incurred expenses of $200 in July, August, and September. The carrier determined that the changes as submitted were reasonable. Even though Mr. C was entitled to benefits for only half the year, he must meet the full $75 deductible. Thus, $75 of this expense constitutes Mr. C's deductible. Medicare would pay $100, which is 80 percent of the remaining $125.

§ 410.161 Part B blood deductible.

(a) *General rules.* (1) As used in this section, "packed red cells" means the red blood cells that remain after plasma is separated from whole blood.

(2) A unit of packed red cells is treated as the equivalent of a pint of whole blood, which in this section is referred to as a unit of whole blood.

(3) Medicare does not pay for the first 3 units of whole blood or units of packed red cells that are furnished under Part B in a calendar year.

(4) The blood deductible does not apply to other blood components such as platelets, fibrinogen, plasma, gamma globulin and serum albumin, or to the costs of processing, storing, and administering blood.

(5) The blood deductible is in addition to the Part B annual deductible specified in § 410.160.

(6) There is also a separate Part A hospital insurance blood deductible. Blood furnished under Part A does not count toward meeting the Part B blood deductible, and blood furnished under Part B does not count toward meeting the Part A blood deductible.

(b) *Beneficiary's responsibility for the first 3 units of blood.* (1) The beneficiary is responsible for the first three units of whole blood or packed red cells received during a calendar year.

(2) If the blood is furnished by a hospital, the rules set forth in § 409.87 (b), (c), and (d) of this chapter apply.

(3) If the blood is furnished by a physician, clinic, or other supplier that has accepted assignment of Medicare benefits, or claims payment under § 424.64 of this chapter because the beneficiary died without assigning benefits, the supplier may charge the beneficiary the reasonable charge for the first 3 units, to the extent that those units are not replaced.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.163 Payment for services furnished to kidney donors.

Notwithstanding any other provisions of this chapter, there are no deductible or coinsurance requirements with respect to services furnished to an individual who donates a kidney for transplant surgery.

§ 410.165 Payment for rural health clinic services and ambulatory surgical center services: Conditions.

(a) Medicare Part B pays for covered rural health clinic services if—

(1) The services are furnished in accordance with the requirements of Subpart X of Part 405 of this chapter and Subpart A of Part 491 of this chapter; and

(2) The clinic files a written request for payment on the form and in the manner prescribed by HCFA.

(b) Medicare Part B pays for covered ambulatory surgical center (ASC) services if—

(1) The services are furnished in accordance with the requirements of Part 416 of this chapter; and

(2) The ASC files a written request for payment on the form and in the manner prescribed by HCFA.

§ 410.170 Payment for home health services, for medical and other health services furnished by a provider or an approved ESRD facility, and for comprehensive outpatient rehabilitation facility (CORF) services: Conditions.

Payment under Medicare Part B, for home health services, for medical and other health services, or for CORF services, may be made to the provider or facility only if the following conditions are met:

(a) *Request for payment.* A written request for payment is filed by or on behalf of the individual to whom the services were furnished.

(b) *Physician certification.* (1) For home health services, a physician provides certification and recertification in accordance with § 424.22 of this chapter.

(2) For medical and other health services, a physician provides certification and recertification in accordance with § 424.24 of this chapter.

(3) For CORF services, a physician provides certification and recertification in accordance with § 424.27 of this chapter.

(c) In the case of home dialysis support services described in § 410.52, the services are furnished in accordance with a written plan prepared and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition as required by § 405.2137(b)(3) of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.175 Alien absent from the United States.

(a) Medicare does not pay Part B benefits for services furnished to an individual who is not a citizen or a national of the United States if those services are furnished in any month for which the individual is not paid monthly social security cash benefits (or would not be paid if he or she were entitled to those benefits) because he or she has been outside the United States continuously for 6 full calendar months.

(b) Payment of benefits resumes with services furnished during the first full calendar month the alien is back in the United States.

[53 FR 6634, Mar. 2, 1988]

PART 412—PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES

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AUTHORITY: Secs. 1102, 1122, 1815(e), 1871, and 1886 of the Social Security Act (42 U.S.C. 1302, 1320a-1, 1395g(e), 1395hh, and 1395ww).

SOURCE: 50 FR 12741, Mar. 29, 1985, unless otherwise noted.

Subpart A—General Provisions

§ 412.1 Scope of part.

(a) *Purpose.* This part implements section 1886(d) of the Act by establishing a prospective payment system for inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983. Under the prospective payment system, payment for the operating costs of inpatient hospital services furnished by hospitals subject to the system (generally, short-term, acute-care hospitals) is made on the basis of prospectively determined rates and applied on a per discharge basis. Payment for other costs related to inpatient hospital services (capital-related costs, kidney acquisition costs incurred by hospitals with approved renal transplantation centers, direct costs of medical education, and, for cost reporting periods beginning on or after October 1, 1984 through any part of a cost reporting period occurring before January 1, 1989, the costs of qualified nonphysician anesthetists' services) is made on a reasonable cost basis. Additional payments are made for outlier cases, bad debts, and indirect medical education costs. Under the prospective payment system, a hospital may keep the difference between its prospective payment rate and its operating costs incurred in furnishing inpatient services, and is at risk for operating costs that exceed its payment rate.

(b) *Summary of content.* This subpart describes the basis of payment for inpatient hospital services under the prospective payment system, and sets forth the general basis of this system. Subpart B sets forth the classifications of hospitals that are included in and excluded from the prospective payment system, and sets forth requirements governing the inclusion or exclusion of hospitals in the system as a result of changes in their classification. Subpart C sets forth certain conditions that must be met for a hospital to receive payment under the prospective payment system. Subpart D sets forth the basic methodology by which prospective payment rates are determined. Subpart E describes the transition rate-setting methods that are used to determine transition payment rates during the first four years of the prospective payment system. Subpart F sets forth the methodology for determining additional payments for outlier cases. Subpart G sets forth rules for special treatment of certain facilities. Subpart H describes the types, amounts, and methods of payment to hospitals under the prospective payment system. Subpart K describes how the prospective payment system is implemented for hospitals located in Puerto Rico.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16786, May 6, 1986; 52 FR 33057, Sept. 1, 1987]

§ 412.2 Basis of payment.

(a) *Payment on a per discharge basis.* Under the prospective payment system, hospitals are paid a predetermined amount per discharge for inpatient hospital services furnished to Medicare beneficiaries. The prospective payment rate for each discharge (as defined in § 412.4) is determined according to the methodology described in Subpart D, E, or G of this part, as appropriate. An additional payment is made, in accordance with Subpart F of this part, for cases that have an atypically long length of stay or are extraordinarily costly to treat.

(b) *Payment in full.* (1) The prospective payment amount paid for inpatient hospital services is the total Medicare payment for the inpatient operating costs (as described in paragraph (c) of this section) incurred in furnishing services covered by the Medicare program.

(2) The full prospective payment amount, as determined under Subpart D, E, or G of this part, is made for each stay during which there is at least one Medicare payable day of care. Payable days of care, for purposes of this paragraph (b)(2), include the following:

(i) Waiver of liability days payable under § 405.330 of this chapter.

(ii) Guarantee of payment days, as authorized under § 409.68 of this chapter, for inpatient hospital services furnished to an individual whom the hospital has reason to believe is entitled to Medicare benefits at the time of admission.

(c) *Inpatient operating costs.* The prospective payment system provides a payment amount for inpatient operating costs, including—

(1) Operating costs for routine services (as described in § 413.53(b) of this chapter), such as the costs of room, board, and routine nursing services;

(2) Operating costs for ancillary services, such as radiology and laboratory services furnished to hospital inpatients;

(3) Special care unit operating costs (intensive care type unit services, as described in § 413.53(b) of this chapter); and

(4) Malpractice insurance costs related to services furnished to inpatients.

(d) *Excluded costs.* The following inpatient hospital costs are excluded from the prospective payment amounts and paid for on a reasonable cost basis:

(1) Capital-related costs, and an allowance for return on equity, as described in §§ 413.130 and 413.157, respectively, of this chapter.

(2) Direct medical education costs, for those approved education programs described in § 413.85 of this chapter.

(3) Costs for direct medical and surgical services of physicians in teaching hospitals exercising the election in § 405.521 of this chapter.

(4) Kidney acquisition costs incurred by certified renal transplantation centers.

(5) For cost reporting periods beginning on or after October 1, 1984 through any part of a cost reporting period occurring before January 1, 1989, costs of qualified nonphysician anesthetists' services.

(e) *Additional payments to hospitals.* In addition to payments based on the prospective payment rates, hospitals will receive payments for the following:

(1) Outlier cases, as described in Subpart F of this part.

(2) The indirect costs of graduate medical education, as specified in Subparts F and H of this part.

(3) Costs excluded from the prospective payment rate under paragraph (d) of this section, as provided in § 412.115.

(4) Bad debts of Medicare beneficiaries, as provided in § 412.115(a).

(5) ESRD beneficiary discharges if such discharges are ten percent or more of the hospital's total Medicare discharges, as provided in § 412.104.

(6) Serving a disproportionate share of low-income patients, as provided in § 412.106.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 52 FR 33057, Sept. 1, 1987; 53 FR 38526, Sept. 30, 1988]

§ 412.4 Discharges and transfers.

(a) *Discharges.* A hospital inpatient is considered discharged when any of the following occurs:

(1) The patient is formally released from the hospital. (Release of the patient to another hospital as described in paragraph (b) of this section, or a leave of absence from the hospital, will not be recognized as a discharge for the purpose of determining payment under the prospective payment system.)

(2) The patient dies in the hospital.

(3) The patient is transferred to a hospital or unit that is excluded from the prospective payment system under Subpart B of this part.

(b) *Transfers.* Except as provided under paragraph (a)(3) of this section, a discharge of a hospital inpatient is not counted for purposes of the prospective payment system when the patient is transferred—

(1) From one inpatient area or unit of the hospital to another area or unit of the hospital;

(2) From the care of a hospital paid under this section to the care of another such hospital; or

(3) From the care of a hospital paid under this section to the care of another hospital—

(i) That is excluded from the prospective payment system because of participation in an approved statewide cost control program or demonstration; or

(ii) Whose first cost reporting period under the prospective payment system has not yet begun.

(c) *Payment in full to the discharging hospital.* The hospital discharging an inpatient (under paragraph (a) of this section) is paid in full, in accordance with § 412.2(b).

(d) *Payment to a hospital transferring an inpatient to another hospital.* (1) A hospital that transfers an inpatient under the circumstances described in paragraph (b)(2) or (b)(3) of this section, is paid a per diem rate for each day of the patient's stay in that hospital, not to exceed the amount that would have been paid under Subparts D and E of this part if the patient had been discharged to another setting. The per diem rate is determined by dividing the appropriate prospective payment rate (as determined under Subparts D and E of this part) by the average length of stay for the specific Diagnosis-Related Group (DRG) into which the case falls.

(2) However, if a discharge is classified into DRG No. 385 (Neonates, died or transferred) or DRG No. 456 (Burns, transferred to another acute care facility), the transferring hospital is paid in accordance with § 412.2(b).

(3) Effective with discharges occurring on or after October 1, 1984, a transferring hospital may qualify for an additional payment for extraordinarily high-cost cases that meet the criteria for cost outliers as described in Subpart F of this part.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 30172, July 24, 1985]

§ 412.6 Cost reporting periods subject to the prospective payment system.

(a) *Initial cost reporting period.* (1) Each subject hospital is paid under the prospective payment system for inpatient hospital services effective with the hospital's first cost reporting period beginning on or after October 1, 1983.

(2) The hospital is paid the applicable prospective payment rate for each discharge occurring on or after the first day of its first cost reporting period subject to the prospective payment system.

(3) If a discharged beneficiary was admitted to the hospital before the first day of the hospital's first cost reporting period subject to prospective payment, the reasonable costs of services furnished before that day are reimbursable under the cost reimbursement provisions of Part 413 of this chapter. For such discharges, the amount otherwise payable under the applicable prospective payment rate is reduced by the amount paid on a reasonable cost basis for inpatient hospital services furnished to that beneficiary during the hospital stay. If the amount reimbursed under reasonable cost exceeds the prospective payment amount, the reduction is limited to the prospective payment amount.

(b) *Changes in cost reporting periods.* HCFA will recognize a change in a hospital's cost reporting period made after November 30, 1982 only if the change has been requested in writing by the hospital and approved by the intermediary in accordance with § 413.24(f)(3) of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986]

§ 412.8 Publication of schedules for determining prospective payment rates.

(a) *Initial prospective payment rates.* Initial prospective payment rates (for the period October 1, 1983 through September 30, 1984) were determined in accordance with documents published in the FEDERAL REGISTER on September 1, 1983 (48 FR

39838), and January 3, 1984 (49 FR 324).

(b) *Annual publication of schedule for determining prospective payment rates.* (1) For periods beginning after September 30, 1984, HCFA will publish annual notices setting forth the methodology and data used, including the percentage increase factor, to determine prospective payment rates applicable to discharges occurring during the Federal fiscal year beginning on or after October 1 of that year.

(2) HCFA will propose changes in the methods, amounts, and factors used to determine prospective payment rates in a FEDERAL REGISTER notice published for public comment not later than the June 1 before the beginning of the Federal fiscal year in which the proposed changes would apply.

(3) HCFA will publish a FEDERAL REGISTER notice setting forth final methods, amounts, and factors for determining prospective payment rates not later than the September 1 before the Federal fiscal year in which the rates would apply.

(4) If HCFA does not meet the September 1 publication date requirement of this paragraph, the prospective payment rates in effect on September 1 of the year in question will apply unchanged for the following Federal fiscal year.

§ 412.10 Changes in the DRG classification system.

(a) *General rule.* HCFA issues changes in the DRG classification system in a Federal Register notice at least annually. Except as specified in paragraphs (c) and (d) of this section, the DRG changes will be effective prospectively with discharges occurring on or after the same date the payment rates are effective.

(b) *Basis for changes in the DRG classification system.* All changes in the DRG classification system are made using the principles established for the DRG system. This means that cases are classified so each DRG is—

(1) Clinically coherent; and

(2) Embraces an acceptable range of resource consumption.

(c) *Interim coverage changes*—(1) *Criteria.* HCFA makes interim changes to the DRG classification system during the Federal fiscal year to incorporate items and services newly covered under Medicare.

(2) *Implementation and effective date.* HCFA issues interim coverage changes through its administrative issuance system and makes the change effective as soon as is administratively feasible.

(3) *Publication for comment.* HCFA publishes any change made under paragraph (c)(1) of this section in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(d) *Interim changes to correct omissions and inequities*—(1) *Criteria.* HCFA makes interim changes to the DRG classification system to correct a serious omission or inequity in the system only if failure to make the changes would have—

(i) A potentially substantial adverse impact on the health and safety of beneficiaries; or

(ii) A significant and unwarranted fiscal impact on hospitals or the Medicare program.

(2) *Publication and effective date.* HCFA publishes these changes in the FEDERAL REGISTER in a final notice with comment period with a prospective effective date. The change is also published for public information in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(e) *Review by ProPAC.* Changes published annually in accordance with paragraph (a) of this section are subject to review and comment by ProPAC upon publication. Interim changes to the DRG classification system that are made in accordance with paragraphs (c) and (d) of this section are subject to review by ProPAC before implementation.

[50 FR 35688, Sept. 3, 1985, as amended at 51 FR 31496, Sept. 3, 1986]

Subpart B—Hospital Services Subject to and Excluded from the Prospective Payment System

§ 412.20 Hospital services subject to the prospective payment system.

(a) Except for services described in paragraph (b) of this section, all covered inpatient hospital services furnished to beneficiaries during subject cost reporting periods are paid for under the prospective payment system.

(b) Inpatient hospital services will not be paid for under the prospective payment system under any of the following circumstances:

(1) The services are furnished by a hospital (or distinct part hospital unit) explicitly excluded from the prospective payment system under §§ 412.23, 412.25, 412.27, 412.29, and 412.32.

(2) The services are emergency services furnished by a nonparticipating hospital in accordance with § 424.103 of this chapter.

(3) The services are paid for by an HMO or competitive medical plan (CMP) that elects not to have HCFA make payments directly to a hospital for inpatient hospital services furnished to the HMO's or CMP's Medicare enrollees, as provided in § 417.240(d) and § 417.586 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 6648, Mar. 2, 1988]

§ 412.22 Excluded hospitals and hospital units: General rules.

(a) *Criteria.* A hospital will be excluded from the prospective payment system if it meets the criteria for one or more of the excluded classifications described in § 412.23.

(b) *Cost reimbursement.* Except for those hospitals specified in paragraph (c) of this section, all excluded hospitals (and excluded distinct part hospital units, as described in §§ 412.23 through 412.29 and § 412.32) are reimbursed under the cost reimbursement rules set forth in Part 413 of this chapter, and will be subject to the ceiling on the rate of hospital cost increases described in § 413.40 of this chapter.

(c) *Special payment provisions.* The following classifications of hospitals are paid under special provisions and therefore are not generally subject to the cost reimbursement or prospective payment rules of this chapter.

(1) Veterans Administration hospitals.

(2) Hospitals reimbursed under State cost control systems approved under Part 403 of this chapter.

(3) Hospitals reimbursed in accordance with demonstration projects authorized under section 402(a) of Pub. L. 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Pub. L. 92-603 (42 U.S.C. 1395b-1 (note)).

(4) Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986]

§ 412.23 Excluded hospitals: Classifications.

Hospitals that meet the requirements for the classifications set forth in this section may not be reimbursed under the prospective payment system.

(a) *Psychiatric hospitals.* A psychiatric hospital must—

(1) Be primarily engaged in providing, by or under the supervision of a psychiatrist, psychiatric services for the diagnosis and treatment of mentally ill persons; and

(2) Meet the conditions of participation for hospitals and special conditions of participation for psychiatric hospitals set forth in Part 482 of this chapter.

(b) *Rehabilitation hospitals.* A rehabilitation hospital must meet the following requirements:

(1) Have a provider agreement under Part 489 of this chapter to participate as a hospital.

(2) Except in the case of a newly participating hospital seeking exclusion for its first 12-month cost reporting period, as described in paragraph (b)(8) of this section, show that during its most recent 12-month cost reporting period, it served an inpatient population of whom at least 75 percent required intensive rehabilitative services

for the treatment of one or more of the following conditions:

(i) Stroke.

(ii) Spinal cord injury.

(iii) Congenital deformity.

(iv) Amputation.

(v) Major multiple trauma.

(vi) Fracture of femur (hip fracture).

(vii) Brain injury.

(viii) Polyarthritis, including rheumatoid arthritis.

(ix) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.

(x) Burns.

(3) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program or assessment.

(4) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social or psychological services, and orthotic and prosthetic services.

(5) Have a director of rehabilitation who—

(i) Provides services to the hospital and its inpatients on a full-time basis;

(ii) Is a doctor of medicine or osteopathy;

(iii) Is licensed under State law to practice medicine or surgery; and

(iv) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical-management of inpatients requiring rehabilitation services.

(6) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(7) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(8) A hospital that seeks exclusion as a rehabilitation hospital for the first full 12-month cost reporting period that occurs after it becomes a Medicare participating hospital may provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b)(2) of this section, instead of showing that it has treated such a population during its most recent 12-month cost reporting period.

(c) *Alcohol/drug hospitals.* If an alcohol/drug hospital meets the following requirements, it is excluded from the prospective payment system for its cost reporting periods beginning before October 1, 1987, but no hospital is excluded for its cost reporting periods beginning during Federal fiscal years 1986 and 1987 unless it was excluded for its cost reporting period beginning during Federal fiscal year 1985:

(1) Treats only patients whose admission to the hospital is required for diagnosis or treatment of alcohol or drug dependence, or both.

(2) Provides treatment using a multidisciplinary team consisting of at least—

(i) A doctor of medicine or osteopathy;

(ii) A registered nurse;

(iii) A certified alcohol/drug counselor; and

(iv) To the extent deemed necessary by the program director, other qualified health professionals (for example, clinical psychologists or social workers).

(3) Ensures that each inpatient is admitted on the authority of, and his or her care is under the direction of, a doctor of medicine or osteopathy who is a member of the hospital's medical staff.

(4) Has a program director to whom the governing body of the hospital has delegated responsibility for maintaining proper standards and assuring quality medical care. The director must be a doctor of medicine or osteopathy who has one year of post-medical school education, or equivalent clinical experience, in the alcohol/drug field, including at least six

months of education or experience in an alcohol/drug treatment inpatient program.

(5) Has a full-time director of nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or with equivalent experience in alcohol/drug treatment.

(6) Has a written treatment plan for each inpatient that is established, reviewed, and revised as needed by the multidisciplinary team. The plan must include a medical assessment and a social/psychological assessment, a record of progress during the course of treatment, and a plan of treatment upon discharge.

(7) Involves inpatients in individual, group, and family educational or therapy programs and other medical or psychological approaches designed to treat the psychological and physical aspects of alcohol/drug dependence and to motivate them to use suitable community support and facilities for long-range rehabilitation.

(8) Coordinates its program with appropriate alcohol/drug abuse programs of other organizations operating in the vicinity such as community mental health centers and Veterans Administration hospitals, voluntary programs such as halfway houses, recovery homes and the Salvation Army, and with self-help groups such as Alcoholics Anonymous, Al-Anon and Alateen.

(d) *Children's hospitals.* A children's hospital must—

(1) Have a provider agreement under Part 489 of this chapter to participate as a hospital; and

(2) Be engaged in furnishing services to inpatients who are predominantly individuals under the age of 18.

(e) *Long-term care hospitals.* A long-term care hospital must—

(1) Have a provider agreement under Part 489 of this chapter to participate as a hospital; and

(2) Have an average length of inpatient stay greater than 25 days—

(i) As computed by dividing the number of total inpatient days (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period; or

(ii) If a change in the hospital's average length of stay is indicated, as computed by the same method for the immediately preceding six-month period.

(f) *Hospitals outside the 50 States, the District of Columbia, or Puerto Rico.* A hospital is excluded from the prospective payment system if it is not located in one of the fifty States, the District of Columbia, or Puerto Rico.

(g) *Hospitals reimbursed under special arrangements.* A hospital must be excluded from prospective payment for inpatient hospital services if it is reimbursed under special arrangement as provided in § 412.22(c).

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 51 FR 22041, June 17, 1986; 51 FR 31496, Sept. 3, 1986; 52 FR 33057, Sept. 1, 1987]

§ 412.25 Excluded distinct part hospital units: Common requirements.

(a) *Basis for exclusion.* In order to be excluded from the prospective payment system, a distinct part psychiatric, rehabilitation, or alcohol/drug unit must meet the following requirements:

(1) Be part of an institution that has in effect an agreement under Part 489 of this chapter to participate as a hospital.

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.

(5) Meet applicable State licensure laws.

(6) Have utilization review standards applicable for the type of care offered in the unit.

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds.

(8) Be serviced by the same fiscal intermediary as the hospital.

(9) Be treated as a separate cost center for cost finding and apportionment purposes.

(10) Use an accounting system that properly allocates costs.

(11) Maintain adequate statistical data to support the basis of allocation.

(12) Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.

(b) *Changes in the size of excluded units.* For purposes of exclusion from the prospective payment system under this section, the number of beds and square footage of each excluded unit will remain the same throughout each cost reporting period, and any change in the number of beds or square footage considered to be part of an excluded unit may be made only at the start of a cost reporting period.

§ 412.27 Distinct part psychiatric units: Additional requirements.

In order to be excluded from the prospective payment system, a distinct part psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Third Edition of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification.

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, occupational therapy, and recreational therapy.

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) *Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) The identification data must include the inpatient's legal status.

(ii) A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(2) *Psychiatric evaluation.* Each inpatient must receive a psychiatric evaluation that must—

(i) Be completed within 60 hours of admission;

(ii) Include a medical history;

(iii) Contain a record of mental status;

(iv) Note the onset of illness and the circumstances leading to admission;

(v) Describe attitudes and behavior;

(vi) Estimate intellectual functioning, memory functioning, and orientation; and

(vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion.

(3) *Treatment plan.*

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis; short-term and long-term goals; the specific treatment modalities utilized; the responsibilities of each member of the treatment team; and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out; and

(ii) The treatment received by the inpatient must be documented in such

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a way as to assure that all active therapeutic efforts are included.

(4) *Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with tne original or revised treatment plan.

(5) *Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

(d) Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning, as follows:

(1) *Personnel.* The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—

(i) Evaluate inpatients;

(ii) Formulate written, individualized, comprehensive treatment plans;

(iii) Provide active treatment measures; and

(iv) Engage in discharge planning.

(2) *Director of inpatient psychiatric services: Medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(i) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(ii) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(3) *Nursing services.* The unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.

(4) *Psychological services.* The unit must provide or have available psychological services to meet the needs of the inpatients. The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.

(5) *Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies

and procedures. Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(6) *Therapeutic activities.* The unit must provide a therapeutic activities program.

(i) The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(ii) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.

§ 412.29 Distinct part rehabilitation units: Additional requirements.

In order to be excluded from the prospective payment system, a distinct part rehabilitation unit must meet the following requirements:

(a) Except as provided in § 412.30, have treated, during its most recent 12-month cost reporting period, an inpatient population of which at least 75 percent required intensive rehabilitative services for the treatment of one or more of the conditions listed in § 412.23(b)(2).

(b) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services.

(d) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(e) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(f) Have a director of rehabilitation who—

(1) Provides services to the unit and to its inpatients for at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.

§ 412.30 Exclusion of new distinct part rehabilitation units and expansion of units already excluded.

(a) *New units.* If a hospital has not previously sought exclusion for any rehabilitation unit, and has obtained approval for added bed capacity under State licensure and under its Medicare certification, it may identify the new beds as a new rehabilitation unit for the first full 12-month cost reporting period during which the beds are used to furnish inpatient care. A unit that is comprised of some beds that were previously licensed and certified, and some new beds, will be recognized as a new rehabilitation unit only if the majority of beds are new. For the first cost reporting period in which a hospital seeks exclusion of a new rehabilitation unit, the hospital may provide a written certification that the inpatient population it intends the unit to serve meets the requirements of § 412.23(b)(2) instead of showing that it has treated such a population during its most recent 12-month cost reporting period.

(b) *Expansion of excluded units.* If a hospital that has an excluded rehabilitation unit has obtained approval for added bed capacity, under State licensure and under its Medicare certification, and seeks to add the new beds to its existing excluded unit for the first full 12-month cost reporting period during which the new beds are used to furnish inpatient care, the hospital may provide a written certification that the inpatient population that the new beds are intended to serve meets the requirements of § 412.23(b)(2) instead of showing that those beds were used to treat such a population during the unit's most recent 12-month cost reporting period.

§ 412.32 Distinct part alcohol/drug units: Additional requirements.

If a distinct part alcohol/drug unit meets the following requirements, it is excluded from the prospective payment system for its cost reporting periods beginning before October 1, 1987, but no unit is excluded for its cost reporting periods beginning during Federal fiscal years 1986 and 1987 unless it was excluded for its cost reporting period beginning in Federal fiscal year 1985:

(a) Treat only patients whose admission to the unit is required for diagnosis or treatment of alcohol or drug dependence, or both.

(b) Provide treatment using a multidisciplinary team consisting of at least—

(1) A doctor of medicine or osteopathy;

(2) A registered nurse;

(3) A certified alcohol/drug counselor; and

(4) To the extent deemed necessary by the unit director, other qualified health professionals (for example, clinical psychologists or social workers).

(c) Ensure that each inpatient is admitted on the authority of, and his or her care is under the direction of, a doctor of medicine or osteopathy who is a member of the unit's medical staff.

(d) Have a director to whom the governing body of the hospital has delegated responsibility for maintaining proper standards and assuring quality medical care. The director must be a doctor of medicine or osteopathy who has one year of post-medical school education, or equivalent clinical experience, in the alcohol/drug field, including at least six months of education or experience in an alcohol/drug treatment inpatient unit.

(e) Have a full-time director of nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or with equivalent experience in alcohol/drug treatment.

(f) Have a written treatment plan for each inpatient that is established, reviewed, and revised as needed by the multidisciplinary team. The plan must include a medical assessment and a social/psychological assessment, a record of progress during the course of treatment, and a plan of treatment upon discharge.

(g) Involve inpatients in individual, group, and family educational or therapy programs and other medical or psychological approaches designed to treat the psychological and physical aspects of alcohol/drug dependence and to motivate them to use suitable community support and facilities for long-range rehabilitation.

(h) Coordinate its program with appropriate alcohol/drug abuse programs of other organizations operating in the vicinity such as community mental health centers and Veterans Administration hospitals, voluntary programs such as halfway houses, recovery homes and the Salvation Army, and with self-help groups such as Alcoholics Anonymous, Al-Anon and Alateen.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 51 FR 31496, Sept. 3, 1986]

Subpart C—Conditions for Payment under the Prospective Payment System

§ 412.40 General requirements.

(a) A hospital must meet the conditions of this subpart to receive payment under the prospective payment system for inpatient hospital services furnished to Medicare beneficiaries.

(b) If a hospital fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, HCFA may, as appropriate—

(1) Withhold Medicare payment (in full or in part) to the hospital until the hospital provides adequate assurances of compliance; or

(2) Terminate the hospital's provider agreement.

§ 412.42 Limitations on charges to beneficiaries.

(a) *Prohibited charges.* A hospital may not charge a beneficiary for any services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment system.

(b) *Permitted charges—Stay covered.* A hospital receiving payment under the prospective payment system for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the following:

(1) The applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter.

(2) Noncovered items and services, furnished at any time during a covered stay, unless they are excluded from coverage only on the basis of the following:

(i) The exclusion of custodial care under § 405.310(g) of this chapter (see paragraph (c) of this section for when charges may be made for custodial care).

(ii) The exclusion of medically unnecessary items and services under § 405.310(k) of this chapter (see paragraphs (c) and (d) of this section for when charges may be made for medically unnecessary items and services).

(iii) The exclusion under § 405.310(m) of this chapter of nonphysician services furnished to hospital inpatients by other than the hospital or a provider or supplier under arrangements made by the hospital.

(iv) The exclusion of items and services furnished when the patient is not entitled to Medicare Part A benefits under Subpart A of Part 406 of this chapter (see paragraph (e) of this section for when charges may be made for items and services furnished when the patient is not entitled to benefits).

(v) The exclusion of items and services furnished after Medicare Part A benefits are exhausted under § 409.61 of this chapter (see paragraph (e) of this section for when charges may be made for items and services furnished after benefits are exhausted).

(c) *Custodial care and medically unnecessary inpatient hospital care.* A hospital may charge a beneficiary for services excluded from coverage on the basis of § 405.310(g) of this chapter (custodial care) or § 405.310(k) of this chapter (medically unnecessary services) and furnished by the hospital after all of the following conditions have been met:

(1) The hospital (acting directly or through its utilization review committee) determines that the beneficiary no longer requires inpatient hospital care. (The phrase "inpatient hospital care" includes cases where a beneficiary needs a SNF level of care, but, under Medicare criteria, a SNF-level bed is not available. This also means that a hospital may find that a patient awaiting SNF placement no longer requires inpatient hospital care because either a SNF-level bed has become available or the patient no longer requires SNF-level care.)

(2) The attending physician agrees with the hospital's determination in writing (for example, by issuing a written discharge order). If the hospital believes that the beneficiary does not require inpatient hospital care but is unable to obtain the agreement of the physician, it may request an immediate review of the case by the PRO. Concurrence by the PRO in the hospital's determination will serve in lieu of the physician's agreement.

(3) The hospital (acting directly or through its utilization review committee) notifies the beneficiary (or person acting on his or her behalf) in writing that—

(i) In the hospital's opinion, and with the attending physician's concurrence or that of the PRO, the beneficiary no longer requires inpatient hospital care;

(ii) Customary charges will be made for continued hospital care beyond the second day following the date of the notice;

(iii) The PRO will make a formal determination on the validity of the hospital's finding if the beneficiary remains in the hospital after he or she is liable for charges;

(iv) The determination of the PRO made after the beneficiary received the purportedly noncovered services will be appealable by the hospital, the attending physician, or the beneficiary under the appeals procedures that apply to PRO determinations affecting Medicare Part A payment; and

(v) The charges for continued care will be invalid and refunded if collected by the hospital, to the extent that a finding is made that the beneficiary required continued care beyond the point indicated by the hospital.

(4) If the beneficiary remains in the hospital after the appropriate notification, and the hospital, the physician who concurred in the hospital determination on which the notice was based, or PRO subsequently finds that the beneficiary requires an acute level of inpatient hospital care, the hospital may not charge the beneficiary for continued care until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence, and notifies the beneficiary, as required in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(d) *Medically unnecessary diagnostic and therapeutic services.* A hospital may charge a beneficiary for diagnostic procedures and studies, and therapeutic procedures and courses of treatment (for example, experimental procedures) that are excluded from coverage under § 405.310(k) of this chapter (medically unnecessary items and services), even though the beneficiary requires continued inpatient hospital care, if those services are furnished after the beneficiary (or the person acting on his or her behalf) has acknowledged in writing that the hospital (acting directly or through its utilization review committee and with the concurrence of the intermediary) has informed him or her as follows:

(1) In the hospital's opinion, which has been agreed to by the intermediary, the services to be furnished are not considered reasonable and necessary under Medicare.

(2) Customary charges will be made if he or she receives the services.

(3) If the beneficiary receives the services, a formal determination on the validity of the hospital's finding is made by the intermediary and, to the extent that the decision requires the exercise of medical judgment, the PRO.

(4) The determination is appealable by the hospital, the attending physician, or the beneficiary under the appeals procedure that applies to determinations affecting Medicare Part A payment.

(5) The charges for the services will be invalid and, to the extent collected, will be refunded by the hospital if the services are found to be covered by Medicare.

(e) *Services furnished on days when the individual is not entitled to Medicare Part A benefits or has exhausted the available benefits.* The hospital may charge the beneficiary its customary charges for noncovered items and services furnished on outlier days (as described in Subpart F of this part) for which payment is denied because the beneficiary is not entitled to Medicare Part A or his or her Medicare Part A benefits are exhausted. (1) If payment is considered for outlier days, the entire stay is reviewed and days up to the number of days in excess of the outlier threshold may be denied on the basis of nonentitlement to Part A or exhaustion of benefits. (2) In applying this rule, the latest days will be denied first.

(f) *Differential for private room or other luxury services.* The hospital may charge the beneficiary the customary charge differential for a private room or other luxury service that is more expensive than is medically required and is furnished for the personal comfort of the beneficiary at his or her request (or the request of the person acting on his or her behalf).

(g) *Review.* (1) The PRO or intermediary may review any cases in which the hospital advises the beneficiary (or the person acting on his or her behalf) of the noncoverage of the services in accordance with paragraph (c)(3) or (d) of this section.

(2) The hospital must identify such cases to the PRO or intermediary in accordance with HCFA instructions.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985]

§ 412.44 Medical review requirements: Admissions and quality review.

Beginning on November 15, 1984, a hospital must have an agreement with a PRO to have the PRO review, on an ongoing basis, the following:

(a) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges.

(b) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter.

(c) The validity of the hospital's diagnostic and procedural information.

(d) The completeness, adequacy, and quality of the services furnished in the hospital.

(e) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

[50 FR 15326, Apr. 17, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 50 FR 41886, Oct. 16, 1985]

§ 412.46 Medical review requirements; DRG validation.

(a) *Physician attestation.* The attending physician must, shortly before, at, or shortly after discharge (but before a claim is submitted), attest to the principal diagnosis, secondary diagnoses, and names of major procedures performed. The information must be in writing in the medical record, and, except as provided in paragraph (b) of this section, the physician must sign the statement. Below the diagnostic and procedural information, and on the same page, the following statement must immediately precede the physician's dated signature:

> "I certify that the narrative descriptions of the principal and secondary diagnoses and the major procedures performed are accurate and complete to the best of my knowledge."

(b) *Alternative signature requirement.* The attending physician's signature, along with the other information required in paragraph (a) of this section, may be provided by electronic means through a hospital data system if the intermediary determines that the hospital data system meets the guidelines established by HCFA.

(c) *Physician acknowledgement.* In addition, when the claim is submitted, the hospital must have on file a current signed and dated acknowledgement from the attending physician that the physician has received the following notice:

> "Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws."

The acknowledgement must have been completed within the year prior to the submission of the claim.

(d) *Sample reviews.* (1) The PRO will review, at least every three months, a random sample of discharges for the previous three-month period or the period since the last review, to verify that the diagnostic and procedural coding, used by the hospital for DRG assignment, is substantiated by the corresponding medical records.

(2) DRG validation must be done on the basis of a review of medical records and, at HCFA's discretion, may take place at the hospital or away from the hospital site.

(e) *Revision of coding.* (1) If the diagnostic and procedural information, attested to by the attending physician, is found to be inconsistent with the hospital's coding or DRG assignment, the hospital's coding for the Medicare claim will be appropriately changed and payments recalculated on the basis of the appropriate DRG assignments.

(2) If the information attested to by the physician as stipulated under paragraph (a) of this section is found not to be correct, the PRO will change the coding and assign the appropriate DRG on the basis of the changed coding.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 53 FR 38527, Sept. 30, 1988]

§ 412.48 Denial of payment as a result of admissions and quality review.

(a) If HCFA determines, on the basis of information supplied by a PRO that a hospital has misrepresented admissions, discharges, or billing information, or has taken an action that results in the unnecessary admission of an individual entitled to benefits under Part A, unnecessary multiple admissions of an individual, or other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries, HCFA may as appropriate—

(1) Deny payment (in whole or in part) under Part A with respect to inpatient hospital services provided with respect to such an unnecessary admission or subsequent readmission of an individual; or

(2) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(b) When payment with respect to admission of an individual patient is denied by a PRO under paragraph (a)(1) of this section, and liability is not waived in accordance with §§ 405.330 through 405.332 of this chapter, notice and appeals are provided under procedures established by HCFA to implement the provisions of section 1155 of the Act, Right to Hearing and Judicial Review.

(c) A determination under paragraph (a) of this section, if it is related to a pattern of inappropriate admissions and billing practices that has the effect of circumventing the prospective payment system, is referred to the Department's Office of Inspector General, for handling in accordance with § 1001.301 of this title.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, 35689, Sept. 3, 1985; 51 FR 34787, Sept. 30, 1986]

§ 412.50 Furnishing of inpatient hospital services directly or under arrangements.

(a) The applicable payments made under the prospective payment system, as described in Subpart H of this part, are payment in full for all inpatient hospital services, as defined in § 409.10 of this chapter, other than physicians' services to individual patients reimbursable on a reasonable charge basis (in accordance with the criteria of § 405.550(b) of this chapter).

(b) HCFA does not pay any provider or supplier other than the hospital for services furnished to a beneficiary who is an inpatient, except for physicians' services reimbursable under § 405.550(b) of this chapter and services of an anesthetist employed by a physician reimbursable under § 405.553(b)(4) of this chapter.

(c) The hospital must furnish all necessary covered services to the beneficiary either directly or under arrangements (as defined in § 409.3 of this chapter).

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 38527, Sept. 30, 1988]

§ 412.52 Reporting and recordkeeping requirements.

All hospitals participating in the prospective payment system must meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986]

Subpart D—Basic Methodology for Determining Federal Prospective Payment Rates

§ 412.60 DRG classification and weighting factors.

(a) *Diagnosis-related groups.* HCFA will establish a classification of inpatient hospital discharges by Diagnosis-Related Groups (DRGs).

(b) *DRG weighting factors.* HCFA will assign, for each DRG, an appropriate weighting factor that reflects the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.

(c) *Assignment of discharges to DRGs.* HCFA will establish a methodology for classifying specific hospital discharges within DRGs which ensures that each hospital discharge is appropriately assigned to a single DRG based on essential data abstract-ed from the inpatient bill for that discharge.

(1) The classification of a particular discharge will, as appropriate, be based on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, procedures performed, and discharge status.

(2) Each discharge will be assigned to only one DRG (related, except as provided in paragraph (c)(3) of this section, to the patient's principal diagnosis) regardless of the number of conditions treated or services furnished during the patient's stay.

(3) When the discharge data submitted by a hospital show a surgical procedure unrelated to a patient's principal diagnosis, the bill will be returned to the hospital for validation and reverification. HCFA's DRG classification system will provide a DRG, and an appropriate weighting factor, for the group of cases for which the unrelated diagnosis and procedure are confirmed.

(d) *Review of DRG assignment.* (1) A hospital has 60 days after the date of the notice of the initial assignment of a discharge to a DRG to request a review of that assignment. The hospital may submit additional information as a part of its request.

(2) The intermediary reviews the hospital's request and any additional information and decides whether a change in the DRG assignment is appropriate. If the intermediary decides that a higher-weighted DRG should be assigned, it must request the appropriate PRO to review the case to verify the change in DRG assignment as specified in § 466.70(e)(2) of this chapter.

(3) Following the 60-day period described in paragraph (d)(1) of this section, the hospital may not submit additional information with respect to the DRG assignment or otherwise revise its claim.

(e) *Revision of DRG classification and weighting factors.* Beginning with discharges in fiscal year 1988, HCFA adjusts the classifications and weighting factors established under paragraphs (a) and (b) of this section at least annually to reflect changes in treatment patterns, technology, and other factors that may change the relative use of hospital resources.

[50 FR 12741, Mar. 29, 1985, as amended at 52 FR 33057, Sept. 1, 1987]

§ 412.62 Federal rates for fiscal year 1984.

(a) *General rule.* HCFA will determine national adjusted DRG prospective payment rates, for each inpatient hospital discharge in fiscal year 1984 involving inpatient hospital services of a hospital in the United States subject to the prospective payment system under Subpart B of this part, and will determine regional adjusted DRG prospective payment rates for such discharges in each region, for which payment may be made under Medicare Part A. Such rates will be determined for hospitals located in urban or rural areas within the United States and within each such region, respectively, as described in paragraphs (b) through (k) of this section.

(b) *Determining allowable individual hospital costs.* HCFA will determine the Medicare allowable operating costs per discharge of inpatient hospital services for each hospital in the data base for the most recent cost reporting period for which data are available.

(c) *Updating for fiscal year 1984.* HCFA will update each amount determined under paragraph (b) of this section for fiscal year 1984 by—

(1) Updating for fiscal year 1983 by the estimated average rate of change of hospital costs industry-wide between the cost reporting period used under paragraph (b) of this section and fiscal year 1983; and

(2) Projecting for fiscal year 1984 by the applicable percentage increase (as defined in § 413.40(c)(3) of this chapter) for fiscal year 1984.

(d) *Standardizing amounts.* HCFA will standardize the amount updated under paragraph (c) of this section for each hospital by—

(1) Adjusting for area variations in case mix among hospitals;

(2) Excluding an estimate of indirect medical education costs;

(3) Adjusting for area variations in hospital wage levels; and

(4) Adjusting for the effects of a higher cost of living for hospitals located in Alaska and Hawaii.

(e) *Computing urban and rural averages.* HCFA will compute an average of the standardized amounts determined under paragraph (d) of this section for urban and rural hospitals in the United States and for urban and rural hospitals in each region.

(f) *Geographic classifications.* (1) For purposes of paragraph (e) of this section, the following definitions apply:

(i) The term "region" means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes.

(ii) The term "urban area" means—

(A) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or

(B) The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(iii) The term "rural area" means any area outside an urban area.

(iv) The phrase "hospital reclassified as rural" means a hospital located in a county that was part of an MSA or NECMA, as defined by the Executive Office of Management and Budget, but is not part of an MSA or NECMA as a result of an Executive Office of Management and Budget redesignation occurring after April 20, 1983.

(2) For hospitals within an MSA or NECMA that crosses census division boundaries, the following provisions apply:

(i) The MSA or NECMA is deemed to belong to the census division in which most of the hospitals within the MSA or NECMA are located.

(ii) If a hospital would receive a lower Federal rate because most of the hospitals are located in a census division with a lower Federal rate than the rate applicable to the census division in which the hospital is located, the payment rate will not be reduced for the hospital's cost reporting period beginning before October 1, 1984.

(iii) If an equal number of hospitals within the MSA or NECMA are located in each census division, such hospitals are deemed to be in the census division with the higher Federal rate.

(g) *Adjusting the average standardized amounts.* HCFA adjusts each of the average standardized amounts determined under paragraphs (c), (d), and (e) of this section by factors representing HCFA's estimates of the following:

(1) The amount of payment that would have been made under Medicare Part B for nonphysician services to hospital inpatients during the first cost reporting period subject to prospective payment were it not for the fact that such services must be furnished either directly by hospitals or under arrangements in order for any Medicare payment to be made after September 30, 1983 (the effective date of § 405.310(m) of this chapter).

(2) The amount of FICA taxes that would be incurred during the first cost reporting period subject to the prospective payment system, by hospitals that had not incurred such taxes for any or all of their employees during the base period described in paragraph (c) of this section.

(h) *Reducing for value of outlier payments.* HCFA reduces each of the adjusted average standardized amounts determined under paragraphs (c) through (g) of this section by a proportion equal to the proportion (estimated by HCFA) of the total amount of payments based on DRG prospective payment rates that are additional payments for outlier cases under Subpart F of this part.

(i) *Maintaining budget neutrality.* (1) HCFA adjusts each of the reduced standardized amounts determined under paragraphs (c) through (h) of this section as required for fiscal year 1984 so that the estimated amount of aggregate payments made, excluding the hospital-specific portion (that is, the total of the Federal portion of transition payments, plus any adjustments and special treatment of certain classes of hospitals for Federal fiscal year 1984) is not greater or less than 25 percent of the payment amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1984 under the Social Security Act as in effect on April 19, 1983.

(2) The aggregate payments considered under this paragraph exclude payments for per case review by a utilization and quality control peer review organization, as allowed under section 1866(a)(1)(F) of the Act.

(j) *Computing Federal rates for urban and rural hospitals in the United States and in each region.* For each discharge classified within a DRG, HCFA will establish a national prospective payment rate and a regional prospective payment rate for each region, as follows:

(1) For hospitals located in an urban area in the United States or in that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraphs (c) through (i) of this section) for hospitals located in an urban area in the United States or in that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in a rural area in the United States or in that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraphs (c) through (i) of this section) for hospitals located in a rural area in the United States or that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(k) *Adjusting for different area wage levels.* HCFA adjusts the proportion (as estimated by HCFA from time to time) of Federal rates computed under paragraph (j) of this section that are attributable to wages and labor-related costs, for area differences in hospital wage levels by a factor (established by HCFA) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (f) of this section) of the hospital compared to the national average hospital wage level.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 53 FR 38527, Sept. 30, 1988]

§ 412.63 Federal rates for fiscal years after Federal fiscal year 1984.

(a) *General rule.* (1) HCFA will determine a national adjusted prospective payment rate for each inpatient hospital discharge in a Federal fiscal year after fiscal year 1984 involving inpatient hospital services of a hospital in the United States subject to the prospective payment system, and will determine a regional adjusted prospective payment rate for such discharges in each region, for which payment may be made under Medicare Part A.

(2) Each such rate will be determined for hospitals located in urban or rural areas within the United States and within each such region respectively, as described in paragraphs (b) through (g) of this section.

(b) *Geographic classifications.* (1) For purposes of this section, the definitions set forth in § 412.62(f) apply.

(2) For hospitals within an MSA or NECMA that crosses census division boundaries, the following provisions apply:

(i) The MSA or NECMA is deemed to belong to the census division in which most of the hospitals within the MSA or NECMA are located.

(ii) A hospital that met the conditions specified in § 412.62(f)(2)(ii) and therefore did not receive a lower Federal rate that would have applied for cost reporting periods beginning before October 1, 1984, will receive the lower Federal rate applicable to all hospitals in the MSA or NECMA in which it is located effective with the hospital's cost reporting period that begins on or after October 1, 1984.

(iii) The higher Federal rate is payable to all hospitals in the MSA or NECMA if an equal number of hospitals within the MSA or NECMA are located in each census division.

(3) For discharges occurring on or after October 1, 1988, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives

the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs or NECMAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs or NECMAs. These EOMB standards are set forth in the notice of final standards for classification of MSAs published in the FEDERAL REGISTER on January 3, 1980 (45 FR 956), and available from HCFA, East High Rise Building, Room 132, 6325 Security Boulevard, Baltimore, Maryland 21207.

(4) For purposes of this section, any change in an MSA or NECMA designation is recognized on the October 1 following the effective date of the change.

(5) For discharges occurring on or after October 1, 1988, for hospitals that consist of two or more separately located inpatient hospital facilities the national adjusted prospective payment rate is based on the geographic location of the hospital facility at which the discharge occurs.

(c) *Updating previous standardized amounts.* (1) HCFA computes an average standardized amount for hospitals in urban areas and rural areas within the United States, and urban areas and rural areas within each region.

(2) Each of those amounts is equal to the respective adjusted average standardized amount computed for fiscal year 1984 under § 412.62(g)—

(i) Increased for fiscal year 1985 by the applicable percentage increase under § 413.40(c) of this chapter;

(ii) Adjusted by the estimated amount of Medicare payment for nonphysician services furnished to hospital inpatients that would have been paid under Part B were it not for the fact that such services must be furnished either directly by hospitals or under arrangements;

(iii) Reduced by a proportion equal to the proportion (estimated by HCFA) of the total amount of prospective payments that are additional payment amounts attributable to outlier cases under Subpart F of this part; and

(iv) Adjusted for budget neutrality under paragraph (h) of this section.

(3) For fiscal year 1986 and thereafter. HCFA computes, for urban and rural hospitals in the United States and for urban and rural hospitals in each region, average standardized amount equal to the respective adjusted average standardized amounts computed for the previous fiscal year—

(i) Increased by the applicable percentage increase determined under paragraphs (d) through (g) of this section;

(ii) Adjusted by the estimated amount of Medicare payment for nonphysician services furnished to hospital inpatients that would have been paid under Part B were it not for the fact that such services must be furnished either directly by hospitals or under arrangements; and

(iii) For discharges occurring on or after October 1, 1985 and before October 1, 1986, reduced by a proportion (estimated by HCFA) of the amount of payments based on the total amount of prospective payments that are additional payment amounts attributable to outlier cases under Subpart F of this part, and for discharges occurring on or after October 1, 1986, reduced by a proportion (estimated by HCFA) of the amount of payments that, based on the total amount of prospective payments for urban hospitals and the total amount of prospective payments for rural hospitals, are additional payments attributable to outlier cases in such hospitals under Subpart F of this part.

(4) For fiscal years 1987 through 1990 HCFA standardizes the average standardized amounts by excluding an estimate of the payments for hospitals that serve a disproportionate share of low-income patients.

(5) For fiscal year 1987 onward, HCFA restandardizes the average standardized amounts by excluding an estimate of indirect medical education payments.

(6) For fiscal year 1988 and thereafter, HCFA computes average standardized amounts for hospitals located in

large urban areas, other urban areas, and rural areas. The term "large urban area" means an MSA with a population of more than 1,000,000 or an NECMA, with a population of more than 970,000 based on the most recent available population data published by the Bureau of the Census.

(d) *Applicable percentage change for fiscal year 1986.* (1) The applicable percentage change for fiscal year 1986 is—

(i) For discharges occurring on or after October 1, 1985 and before May 1. 1986, zero percent; and

(ii) For discharges occurring on or after May 1, 1986, one-half of one percent.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1986, the applicable percentage increase for fiscal year 1986 is deemed to have been one-half of one percent.

(e) *Applicable percentage change for fiscal year 1987.* The applicable percentage change for fiscal year 1987 is 1.15 percent.

(f) *Applicable percentage change for fiscal year 1988.* (1) The applicable percentage change for fiscal year 1988 is—

(i) For discharges occurring on or after October 1, 1987 and before November 21, 1987, zero percent;

(ii) For discharges occurring on or after November 21, 1987 and before April 1, 1988, 2.7 percent; and

(iii) For discharges occurring on or after April 1, 1988 and before October 1, 1988—

(A) 3.0 percent for hospitals located in rural areas;

(B) 1.5 percent for hospitals located in large urban areas; and

(C) 1.0 percent for hospitals located in other urban areas.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1988 (for Federal fiscal year 1989), the applicable percentage change for fiscal year 1988 is deemed to have been—

(i) 3.0 percent for hospitals located in rural areas;

(ii) 1.5 percent for hospitals located in large urban areas; and

(iii) 1.0 percent for hospitals located in other urban areas.

(g) *Applicable percentage change for fiscal year 1989.* The applicable percentage change for fiscal year 1989 is the percentage increase in the market basket index (as described in § 413.40(c)(3)(ii))—

(1) Minus 1.5 percentage points for hospitals located in rural areas;

(2) Minus 2.0 percentage points for hospitals in large urban areas; and

(3) Minus 2.5 percentage points for hospitals in other urban areas.

(h) *Applicable percentage change for fiscal year 1990 and following.* The applicable percentage change for FY 1990 and each subsequent fiscal year for hospitals in all areas is the percentage increase in the market basket index (as described in § 413.40(c)(3)(ii)).

(i) *Maintaining budget neutrality for fiscal year 1985.* (1) For fiscal year 1985, HCFA will adjust each of the reduced standardized amounts determined under paragraph (c) of this section as required for fiscal year 1985 to ensure that the estimated amount of aggregate payments made, excluding the hospital-specific portion (that is, the total of the Federal portion of transition payments, plus any adjustments and special treatment of certain classes of hospitals for fiscal year 1985) is not greater or less than 50 percent of the payment amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1985 under the law as in effect on April 19, 1983.

(2) The aggregate payments considered under this paragraph exclude payments for per case review by a utilization and quality control peer review organization, as allowed under section 1866(a)(1)(F) of the Act.

(j) *Computing Federal rates for large urban, other urban, and rural hospitals.* For each discharge classified within a DRG, HCFA establishes for the fiscal year a national prospective payment rate and a regional prospective payment rate, for each region, as follows:

(1) For hospitals located in a large urban or other urban area in the United States or that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a large urban or other urban area in the United States or in that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in a rural area in the United States or that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a rural area in the United States or that region; and

(ii) The weighting factor (determined under § 412.60(b)) for that DRG.

(k) *Adjusting for different area wage levels.* HCFA adjusts the proportion (as estimated by HCFA from time to time) of Federal rates computed under paragraph (j) of this section that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by HCFA) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the national average hospital wage level.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16786, May 6, 1986; 51 FR 31496, Sept. 3, 1986; 51 FR 34793, Sept. 30, 1986; 51 FR 42234, Nov. 24, 1986; 52 FR 23834, June 25, 1987; 52 FR 33057, Sept. 1, 1987; 53 FR 38527, Sept. 30, 1988]

Subpart E—Determination of Transition Period Payment Rates

§ 412.70 General description.

(a) *Basic rules.* (1) During the initial four-year transition period, payments to all hospitals paid under the prospective payment system are based on a combination of the Federal prospective payment rates, as determined under Subpart D of this part, and hospital-specific rates determined under this subpart.

(2) For the first two years of the transition period, both portions of the payment rates are also adjusted to ensure budget neutrality.

(3) At the end of the transition period (that is, for cost reporting periods beginning on or after October 1, 1987), payments are based on the national prospective payment rates determined under Subpart D of this part, except for payments that may be made under the special treatment provisions of Subpart G of this part.

(b) *Payment amounts based on the hospital-specific portion and the Federal portion.* For discharges occurring in cost reporting periods beginning on or after October 1, 1983 and before October 1, 1987, the Medicare transition payment rate for a particular covered discharge equals a blend of the applicable portion of the hospital-specific rate, as determined under § 412.73, plus the applicable portions of the Federal national and regional prospective payment rates, as described in paragraph (c) of this section, and summarized in the Table. Payments to new hospitals are based on the Federal national and regional prospective payment rates, as described in paragraph (d) of this section.

(c) *Amount of blended portions.*[1] The blends of hospital-specific and Federal portions are as follows:

(1) For cost reporting periods beginning on or after October 1, 1983 and before October 1, 1984, the blend is—

(i) 75 percent of the hospital-specific rate; and

(ii) 25 percent of the appropriate Federal prospective payment rate.

(2) For cost reporting periods beginning on or after October 1, 1984 and before October 1, 1985, the blend is—

(i) 50 percent of the hospital-specific rate; and

(ii) 50 percent of the appropriate Federal prospective payment rate.

(3) For cost reporting periods beginning on or after October 1, 1985 and before October 1, 1986, the blend is as follows:

(i) For the first seven months of the cost reporting period, the blend is—

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[1] For purposes of this paragraph and §§ 412.80(a)(1)(ii)(B) and 412.82(c), see section 9102(d)(4) of Pub. L. 99-272 for special provisions concerning the transition period applicable to hospitals in the State of Oregon.

(A) 50 percent of the hospital-specific rate; and

(B) 50 percent of the appropriate Federal prospective payment rate.

(ii) For the remaining five months of the cost reporting period, the blend is—

(A) 45 percent of the hospital-specific rate; and

(B) 55 percent of the appropriate Federal prospective payment rate.

(4) For cost reporting periods beginning on or after October 1, 1986 and before October 1, 1987, the blend is—

(i) 25 percent of the hospital-specific rate; and

(ii) 75 percent of the appropriate Federal prospective payment rate.

(5) The appropriate Federal prospective payment rate is a combined regional and national rate and changes with the Federal fiscal year. For Federal fiscal year 1984, which begins October 1, 1983, the Federal prospective payment rate is 100 percent regional. For Federal fiscal years 1985 and 1986, which begin October 1, 1984 and October 1, 1985, respectively, the combined rate is 75 percent regional and 25 percent national. For Federal fiscal year 1987, which begins October 1, 1986, the combined rate is 50 percent regional and 50 percent national. Effective with Federal fiscal year 1988, which begins October 1, 1987, the Federal prospective payment rate is 100 percent national except as provided in paragraph (c)(6) of this section.

(6) For discharges occurring on or after April 1, 1988 and before October 1, 1990, payments to a hospital are based on the greater of the national average standardized amount or the sum of 85 percent of the national average standardized amount and 15 percent of the average standardized amount for the region in which the hospital is located.

TABLE—SUMMARY OF HOSPITAL-SPECIFIC AND FEDERAL PORTION PERCENTAGES FOR DETERMINING TRANSITION PAYMENT RATES

Cost reporting period beginnng on or after	Hospital-specific portion percentage	Federal portion percentage*
October 1, 1983	75	25
October 1, 1984	50	50
October 1, 1985—		
The first seven months of the cost reporting period	50	50
The remaining five months of the cost reporting period	45	55
October 1, 1986	25	75
October 1, 1987	0	100

* NOTE: The Federal portion percentages are applied to the combined national or regional prospective payment rates, as appropriate, as determined under Subpart D of this part for the Federal fiscal year in which the discharge occurs.

(d) *Blended portions for new hospitals.* The prospective payment rates for new hospitals are a blend of the Federal regional and national rates as follows:

(1) For discharges occurring on or after October 1, 1983, and before October 1, 1984, the prospective payment rate equals the appropriate Federal regional rate.

(2) For discharges occurring on or after October 1, 1984 and before October 1, 1986, the prospective payment rate is a blend of—

(i) 75 percent of the appropriate Federal regional prospective payment rate; and

(ii) 25 perceht of the appropriate Federal national rate.

(3) For discharges occurring on or after October 1, 1986 and before October 1, 1987, the prospective payment rate is a blend of—

(i) 50 percent of the appropriate Federal regional prospective payment rate; and

(ii) 50 percent of the appropriate Federal national prospective payment rate.

(4) For discharges occurring on or after October 1, 1987, the prospective payment rate equals the appropriate Federal national rate except as provided in paragraph (d)(5) of this section.

(5) For discharges occurring on or after April 1, 1988 and before October 1, 1990, payments to a hospital are based on the greater of the national

average standardized amount or the sum of 85 percent of the national average standardized amount and 15 percent of the average standardized amount for the region in which the hospital is located.

[51 FR 16786, May 6, 1986, as amended at 53 FR 38528, Sept. 30, 1988]

§ 412.71 Determination of base-year costs.

(a) *Base-year costs.* (1) For each hospital, the intermediary will estimate the hospital's Medicare Part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period ending on or after September 30, 1982 and before September 30, 1983.

(2) If the hospital's last cost reporting period ending before September 30, 1983 is for less than 12 months, the base period will be the hospital's most recent 12-month or longer cost reporting period ending before such short reporting period, with an appropriate adjustment for inflation. (The rules applicable to new hospitals are set forth in § 412.74.)

(b) *Modifications to base-year costs.* Prior to determining the hospital-specific rate, the intermediary will adjust the hospital's estimated base-year inpatient operating costs, as necessary, to include malpractice insurance costs as described in § 413.55 of this chapter, and exclude the following:

(1) Nursing differential costs as described in § 405.430[1] of this chapter.

(2) Medical education costs as described in § 413.85 of this chapter.

(3) Capital-related costs as described in § 413.130 of this chapter.

(4) Kidney acquisition costs incurred by hospitals approved as renal transplantation centers as described in § 412.100. Kidney acquisition costs in the base year will be determined by multiplying the hospital's average kidney acquisition cost per kidney times the number of kidney transplants covered by Medicare Part A during the base period.

(5) Higher costs that were incurred for purposes of increasing base-year costs.

(6) One-time nonrecurring higher costs or revenue offsets that have the effect of distorting base-year costs as an appropriate basis for computing the hospital-specific rate.

(7) Higher costs that result from changes in hospital accounting principles initiated in the base year.

(8) For cost reporting periods beginning on or after October 1, 1984 through any part of a cost reporting period occurring before January 1, 1989, the cost of qualified nonphysician anesthetists' services as described in § 412.113(c).

(c) *Hospital's request for adjustment of base-year costs.* (1) Before the date it becomes subject to the prospective payment system, a hospital may request the intermediary to further adjust its estimated base-period costs to take into account the following:

(i) Services paid for under Medicare Part B during the hospital's base year that will be paid for under prospective payments. The base-year costs may be increased to include estimated payments for certain services previously billed as physicians' services before the effective date of § 405.550(b) of this chapter, and estimated payments for nonphysicians' services that were not furnished either directly or under arrangements before October 1, 1983 (the effective date of § 405.310(m) of this chapter), but may not include the costs of anesthetists' services for which a physician employer continues to bill under § 405.553(b)(4) of this chapter.

(ii) The payment of FICA taxes during cost reporting periods subject to the prospective payment system, if the hospital had not paid such taxes for all its employees during its base period and will be required to participate effective January 1, 1984.

(2) If a hospital requests that its base-period costs be adjusted under paragraph (c)(1) of this section, it must timely provide the intermediary with sufficient documentation to justify the adjustment, and adequate data to compute the adjusted costs. The intermediary will decide whether to use part or all of the data on the basis of audit, survey and other information available.

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[1] Section 405.430 was removed at 48 FR 39811, Sept. 1, 1983.

(d) *Intermediary's determination.* The intermediary will use the best data available at the time in estimating each hospital's base-year costs and the modifications to those costs authorized by paragraphs (b) and (c) of this section. The intermediary's estimate of base-year costs and modifications thereto is final and may not be changed after the first day of the first cost reporting period beginning on or after October 1, 1983, except as provided in § 412.72.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 52 FR 33057, Sept. 1, 1987]

§ 412.72 Modification of base-year costs.

(a) *Bases for modification of base-year costs.* Base-year costs as determined under § 412.71(d) may be modified under the following circumstances:

(1) *Inadvertent omissions.* (i) A hospital that becomes subject to the prospective payment system beginning on or after October 1, 1983 and before November 16, 1983 has until November 15, 1983 to request its intermediary to reestimate its base-period costs to take into account inadvertent omissions in its previous submissions to the intermediary related to changes made by the prospective payment legislation for purposes of estimating the base-period costs.

(ii) The intermediary may also initiate changes to the estimation—

(A) For any reason before the date the hospital becomes subject to prospective payment; and

(B) Before November 16, 1983, for corrections to take into account inadvertent omissions in the hospital's previous submissions related to changes made by the prospective payment legislation for purposes of estimating the base-period costs.

(iii) Such omissions pertain to adjustments to exclude capital-related costs and the direct medical education costs of approved educational activities and to adjustments specified in § 412.71(c).

(iv) The intermediary must notify the provider of any change to the hospital-specific amount as a result of the provider's request within 30 days of receipt of the additional data.

(v) Any change to base-period costs made under this paragraph (a)(1) will be made effective retroactively, beginning with the first day of the affected hospital's fiscal year.

(2) *Correction of mathematical errors of calculations.* (i) The hospital must report mathematical errors of calculations to the intermediary within 90 days of the intermediary's notification to the hospital of the hospital's payments rates.

(ii) The intermediary may also identify such errors and initiate their correction during this period.

(iii) The intermediary will either make an appropriate adjustment or notify the hospital that no adjustment is warranted within 30 days of receipt of the hospital's report of an error.

(iv) Corrections of errors of calculation will be effective with the first day of the hospital's first cost reporting period subject to the prospective payment system.

(3) *Recognition of additional costs.* (i) The intermediary may adjust base-period costs to take into account additional costs recognized as allowable costs for the hospital's base year as the result of any of the following:

(A) A reopening and revision of the hospital's base-year notice of amount of program reimbursement under §§ 405.1885 through 405.1889 of this chapter.

(B) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(C) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of HCFA under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(D) An administrative or judicial review decision under §§ 405.1831, 405.1871, or 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(ii) The intermediary will recalculate the hospital's base-year costs, incorporating the additional costs recognized as allowable for the hospital's base year. Adjustments to base-year costs to take into account these additional costs—

(A) Will be effective with the first day of the hospital's first cost reporting period beginning on or after the date of the revision, order or finding, or review decision; and

(B) Will not be used to recalculate the hospital-specific portion as determined for fiscal years beginning before the date of the revision, order or finding, or review decision.

(4) *Successful appeal.* The intermediary may modify base-year costs to take into account a successful appeal relating to modifications to base-year costs that were made under § 412.71(b). If a hospital successfully contests a modification to base-year costs—

(i) The intermediary will recalculate the hospital's base-year costs to reflect the modification determined appropriate as a result of the appeal; and

(ii) Such adjustments will be effective retroactively to the time of the intermediary's initial estimation of base-year costs.

(5) *Unlawfully claimed costs.* The intermediary may modify base-year costs to exclude costs that were unlawfully claimed as determined as a result of criminal conviction, imposition of a civil judgment under the False Claims Act (31 U.S.C. 3729-3731), or a proceeding for exclusion from the Medicare program. In addition to adjusting base-year costs, HCFA will recover both the excess costs reimbursed for the base period and the additional amounts paid due to the inappropriate increase of the hospital-specific portion of the hospital's transition payment rates. The amount to be recovered will be computed on the basis of the final resolution of the amount of the inappropriate base-year costs.

(b) *Right to administrative and judicial review.* (1) An intermediary's estimation of a hospital's base-year costs, and modifications, made for purposes of determining the hospital-specific rate, are subject to administrative and judicial review. Review will be available to a hospital upon receipt of its notice of amount of program reimbursement following the close of its cost reporting period, but only with respect to whether the intermediary followed the provisions of §§ 412.71 and 412.72. (Sections 405.1803 and 405.1807 of this chapter set forth the rules for intermediary determinations and notice of amount of program reimbursement and the effect of those determinations.)

(2) In any administrative or judicial review of whether the intermediary used the best data available at the time, as required by § 412.71(d), an intermediary's estimation will be revised on the basis of this review only if the estimation was unreasonable and clearly erroneous in light of the data available at the time the estimation was made.

(3) Specifically excluded from administrative or judicial review are any issues based on data, information, or arguments not presented to the intermediary at the time of the estimation.

§ 412.73 Determination of the hospital-specific rate.

(a) *Costs on a per discharge basis.* The intermediary will determine the hospital's estimated adjusted base-year operating cost per discharge by dividing the total adjusted operating costs by the number of discharges in the base period.

(b) *Case-mix adjustment.* The intermediary will divide the adjusted base-year costs by the hospital's 1981 case-mix index. If the hospital's case-mix index is statistically unreliable (as determined by HCFA), the hospital's base-year costs will be divided by the lower of the following:

(1) The hospital's estimated case-mix index.

(2) The average case-mix index for the appropriate classifications of all hospitals subject to cost limits established under § 413.30 of this chapter for cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983.

(c) *Updating base-year costs*—(1) *For Federal fiscal year 1984.* The case-mix adjusted base-year cost per discharge will be updated by the applicable updating factor, that is, the target rate percentage determined under § 413.40(c)(3) of this chapter, as adjusted for budget neutrality.

(2) *For Federal fiscal year 1985.* The amount determined under paragraph (c)(1) of this section will be updated by the applicable updating factor, as adjusted for budget neutrality.

(3) *For Federal fiscal year 1986.* (i) The amount determined under paragraph (c)(2) of this section is updated by—

(A) Zero percent for the first seven months of the hospital's cost reporting period; and

(B) One-half of one percent for the remaining five months of the hospital's cost reporting period.

(ii) For purposes of determining the updated base-year costs for cost reporting periods beginning in Federal fiscal year 1987 (that is, on or after October 1, 1986 and before October 1, 1987), the update factor for the previous cost reporting period is deemed to have been one-half of one percent.

(4) *For Federal fiscal year 1987.* The amount determined under paragraph (c)(3)(ii) of this section is updated by 1.15 percent.

(5) *For Federal fiscal year 1988.* (i) For purposes of determining the prospective payment rates for sole community hospitals under § 412.92(d) for cost reporting periods beginning in Federal fiscal year 1988 (that is, on or after October 1, 1987 and before October 1, 1988), the base-year cost per discharge is undated as follows:

(A) For the first 51 days of the hospital's cost reporting period, by zero percent.

(B) For the next 132 days of the hospital's cost reporting period, by 2.7 percent.

(C) For the remainder of the hospital's cost reporting period, by—

(*1*) 3.0 percent for hospitals located in rural areas;

(*2*) 1.5 percent for hospitals located in large urban areas; and

(*3*) 1.0 percent for hospitals located in other urban areas.

(ii) For purposes of determining the updated base-year costs for cost reporting periods beginning in Federal fiscal year 1989 (that is, beginning on or after October 1, 1988 and before October 1, 1989), the update factor for the cost reporting period beginning during federal fiscal year 1988 is deemed to have been—

(A) 3.0 percent for hospitals located in rural areas;

(B) 1.5 percent for hospitals located in large urban areas; and

(C) 1.0 percent for hospitals located in other urban areas.

(6) *For Federal fiscal years 1989 and following.* For Federal fiscal years 1989 and following, the update factor is determined using the methodology set forth in § 412.63(g) and (h).

(d) *Budget neutrality*—(1) *Federal fiscal year 1984.* For cost reporting periods beginning on or after October 1, 1983 and before October 1, 1984, HCFA will adjust the target rate percentage used under paragraph (c)(1) of this section. This adjustment will be based on a factor actuarially estimated to ensure that the estimated amount of aggregate Medicare payments based on the hospital-specific portion of the transition payment rates is neither greater nor less than 75 percent of the amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1984 under the law in effect before April 20, 1983.

(2) *Federal fiscal year 1985.* For cost reporting periods beginning on or after October 1, 1984 and before October 1, 1985, HCFA will adjust the target rate percentage used under paragraph (c)(2) of this section. This adjustment is based on a factor actuarially estimated to ensure that the estimated amount of aggregate Medicare payment based on the hospital-specific portion of the transition payment rates is neither greater nor less than 50 percent of the amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1985 under the Social Security Act as in effect on April 19, 1983.

(e) *DRG adjustment.* The applicable hospital-specific cost per discharge will be multiplied by the appropriate DRG weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16787, May 6, 1986; 51 FR 34793, Sept. 30, 1986; 51 FR 42234, Nov. 24, 1986; 52 FR 33057, Sept. 1, 1987; 53 FR 38528, Sept. 30, 1988]

§ 412.74 Determination of transition payment rates for new hospitals.

(a) For purposes of this section, a new hospital is a hospital that meets either of the following requirements:

(1) The hospital—

(i) Is newly participating in the Medicare program (under previous and present ownership); and

(ii) Does not have a 12-month cost reporting period ending before September 30, 1983.

(2) The hospital is under new ownership and can document to the satisfaction of its intermediary that—

(i) Its base period reflects previous ownership and control under which the hospital's operation was deliberately phased out in expectation of sale or termination of operations;

(ii) Its occupancy rate during the current period is 150 percent of the occupancy rate during the base year;

(iii) Previous ownership and management took deliberate steps to curtail services in the base period by reducing operations, laying off or transferring employees to non-inpatient areas, reducing physician staff, and reducing inpatient admissions; and

(iv) The change in ownership and the corresponding growth in inpatient services and occupancy occurred between the base period and the first prospective payment period.

(b) For purposes of computing transition payment rates for a new hospital, HCFA will not use the hospital-specific portion of the prospective payment rate. Payments to new providers will be based solely on the Federal regional and national prospective payment rates, as described in § 412.70(d).

§ 412.76 Recovery of excess transition period payment amounts resulting from unlawful claims.

If a hospital's base-year costs, as estimated for purposes of determining the hospital-specific portion, are determined, by criminal conviction or imposition of a civil money penalty or assessment, to include costs that were unlawfully claimed, the hospital's base-period costs will be adjusted to remove the effect of the excess costs, and HCFA will recover both the excess costs reimbursed for the base period and the additional amounts paid due to the inappropriate increase of the hospital-specific portion of the hospital's transition payment rates.

Subpart F—Payment for Outlier Cases

§ 412.80 General provisions.

(a) *Basic rule.* (1) Except as provided in paragraph (a)(2) of this section concerning transferring hospitals, HCFA provides for additional payment, approximating a hospital's marginal cost of care beyond thresholds specified by HCFA, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if either of the following conditions is met:

(i) The beneficiary's length of stay (including days at the SNF level of care if a SNF bed is not available in the area) exceeds the mean length-of-stay for the applicable DRG by the lesser of the following:

(A) A fixed number of days, as specified by HCFA.

(B) A fixed number of standard deviations, as specified by HCFA.

(ii) The beneficiary's length of stay does not exceed criteria established under paragraph (a)(1)(i) of this section, but the hospital's charges for covered services furnished to the beneficiary, adjusted to cost by applying a cost-to-charge ratio as described in § 412.84(h), exceed the greater of the following:

(A) A fixed dollar amount (adjusted for area wage levels) as specified by HCFA.

(B) A fixed multiple of the Federal prospective payment rate. During the transition period, the Federal rate is a combination of the national rate and regional rate as follows:

Federal fiscal year	Regional rate percentage	National rate percentage
October 1, 1983	100	0
October 1, 1984	75	25
October 1, 1985	75	25
October 1, 1986	50	50
October 1, 1987	0	100

(2) *Outlier cases in transferring hospitals.* HCFA provides cost outlier payments to a transferring hospital that does not receive payment under § 412.2(b) for discharges specified in § 412.4(d)(2), if the hospital's charges for covered services furnished to the beneficiary, adjusted to cost by applying a cost-to-charge ratio as described in § 412.84(h), exceed the greater of the criteria specified in paragraph (a)(1)(ii) of this section.

(2) *Outlier cases in transferring hospitals.* HCFA will provide cost outlier payments to a transferring hospital that does not receive payment under § 412.2(b) for discharges specified in § 412.4(d)(2), if the hospital's charges for covered services furnished to the beneficiary, adjusted to cost by applying a national cost/charge ratio, exceed the greater of the criteria specified in paragraph (a)(1)(ii) of this section.

(b) *Publication and revision of outlier criteria.* HCFA will issue threshold criteria for determining outlier payment in the annual notice of prospective payment rates published in accordance with § 412.8(b).

(c) *Relation to indirect medical education costs and hospitals that serve a disproportionate share of low-income patients.* The outlier payment amounts are included in total DRG revenue for purposes of determining payments for indirect medical education costs under § 412.118(b) and to hospitals that serve a disproportionate share of low-income patients under § 412.106.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16787, May 6, 1986; 51 FR 31496, Sept. 3, 1986; 53 FR 38529, Sept. 30, 1988]

§ 412.82 Payment for extended length-of-stay cases (day outliers).

(a) If the hospital stay reflected by a discharge includes covered days of care beyond the applicable threshold criterion, the intermediary will make an additional payment, on a per diem basis, to the discharging hospital for those days. A special request or submission by the hospital is not necessary to initiate this payment. However, a hospital may request payment for day outliers before the medical review required in paragraph (b) of this section.

(b) The PRO must review and approve to the extent required by HCFA—

(1) The medical necessity and appropriateness of the admission and outlier services in the context of the entire stay;

(2) The validity of the diagnostic and procedural coding; and

(3) The granting of grace days.

(c) Except as provided in paragraph (d) of this section or § 412.86, the per diem payment made under paragraph (a) of this section is derived by first taking 60 percent of the average per diem payment for the applicable DRG, as calculated by dividing the Federal prospective payment rate determined under Subpart D of this part by the mean length-of-stay for that DRG. The resulting amount is then multiplied by the applicable Federal portion of the blend as follows:

Cost reporting periods beginning on or after	Federal portion (percent)
October 1, 1983	25
October 1, 1984	50
October 1, 1985	
The first seven months of the cost reporting period	50
The remaining five months of the cost reporting period	55
October 1, 1986	75
October 1, 1987	100

(d) For discharges occurring on or after April 1, 1988 and before October 1, 1989, the per diem payment made under paragraph (a) of this section for the DRGs related to burn cases, which are identified in the most recent annual notice of prospective payment rates published in accordance with § 412.8(b), is derived under the provisions of paragraph (c) of this section except that the calculation is made using 90 percent of the average per diem payment of the applicable DRG.

(e) Any days in a covered stay identified as noncovered reduce the number of days reimbursed at the day outlier rate but not to exceed the number of days that occur after the day outlier threshold.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 15326, Apr. 17, 1985; 50 FR 35689, Sept. 3, 1985; 51 FR 16787, May 6, 1986; 53 FR 38529, Sept. 30, 1988]

§ 412.84 Payment for extraordinarily high-cost cases (cost outliers).

(a) A hospital may request its intermediary to make an additional payment for inpatient hospital services that meet the criteria established in accordance with § 412.80(a)(1)(ii).

(b) The hospital must request additional payment—

(1) With initial submission of the bill; or

(2) Within 60 days of receipt of the intermediary's initial determination.

(c) Except as specified in paragraph (e) of this section, an additional payment for a cost outlier case is made prior to medical review.

(d) As described in paragraph (f) of this section, the PRO reviews a sample of cost outlier cases after payment. The charges for any services identified as noncovered through this review will be denied and any outlier payment made for these services will be recovered, as appropriate, after a determination as to the provider's liability has been made.

(e) If the PRO finds a pattern of inappropriate utilization by a hospital, all cost outlier cases from that hospital are subject to medical review, and this review may be conducted prior to payment until the PRO determines that appropriate corrective actions have been taken.

(f) The PRO reviews the cost outlier cases, using the medical records and itemized charges, to verify the following:

(1) The admission was medically necessary and appropriate.

(2) Services were medically necessary and delivered in the most appropriate setting.

(3) Services were ordered by the physician, actually furnished, and not duplicatively billed.

(4) The diagnostic and procedural codings are correct.

(g) The intermediary bases the cost of the discharge on the billed charges for covered inpatient services adjusted by a cost-to-charge ratio as described in paragraph (h) of this section. The cost is adjusted further to exclude an estimate of indirect medical education costs, and payments for hospitals that serve a disproportionate share of low-income patients, and to include the reasonable charges for nonphysician services billed by an outside supplier in accordance with § 489.23(c)(3) of this chapter.

(h) The cost-to-charge ratio used to adjust covered charges is computed annually by the intermediary for each hospital based on the latest available settled cost report for that hospital and charge data for the same time period as that covered by the cost report. Statewide cost-to-charge ratios are used in those instances in which a hospital's cost-to-charge ratio falls outside reasonable parameters. HCFA sets forth these parameters and the Statewide cost-to-charge ratios in each year's annual notice of prospective payment rates published under § 412.8(b).

(i) If any of the services are determined to be noncovered, the charges for these services will be deducted from the requested amount of reimbursement but not to exceed the amount claimed above the cost outlier threshold.

(j) Except as provided in paragraph (k) of this section, the additional amount is derived by first taking 75 percent of the difference between the hospital's adjusted cost for the discharge (as determined under paragraph (g) of this section) and the threshold criteria established under § 412.80(a)(1)(ii). The resulting amount will then be multiplied by the applicable Federal portion of the blend as indicated in § 412.82(c).

(k) For discharges occurring on or after April 1, 1988 and before October 1, 1989, the additional payment amount for the DRGs related to burn cases, which are identified in the most recent annual notice of prospective payment rates published in accordance with § 412.8(b), is computed under the provisions of paragraph (i) of this section except that the payment is made using 90 percent of the difference between the hospital's adjusted cost for the discharge and the threshold criteria.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 51 FR 31496, Sept. 3, 1986; 53 FR 38529, Sept. 30, 1988]

§ 412.86 Payment for extraordinarily high-cost day outliers.

If a discharge that qualifies for an additional payment under the provisions of § 412.82 has charges adjusted to costs that exceed the cost outlier threshold criteria for an extraordinarily high-cost case as set forth in § 412.80(a)(1)(ii), the additional payment made for the discharge is the greater of—

(a) The applicable per diem payment computed under § 412.82 (c) or (d); or

(b) The payment that would be made under § 412.84 (i) or (j) if the case had not met the day outlier criteria threshold set forth in § 412.80(a)(1)(i).

[53 FR 38529, Sept. 30, 1988]

Subpart G—Special Treatment of Certain Facilities

§ 412.90 General rules.

(a) *Sole community hospitals.* HCFA may adjust the prospective payment rates determined under Subpart D or E of this part if a hospital, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, is the sole source of inpatient hospital services reasonably available in a geographic area to Medicare beneficiaries. If a hospital meets the criteria for such an exception under § 412.92(a), its prospective payment rates will be determined under § 412.92(d).

(b) *Hospitals involved extensively in treatment for and research on cancer.* HCFA may adjust the prospective payment rates determined under Subpart D or E of this part if a hospital is involved extensively in treatment for and research on cancer. Criteria for identifying such hospitals are set forth in § 412.94(a).

(c) *Referral center.* HCFA may make an adjustment to the prospective payment rates determined under Subpart D or E of this part if a hospital acts as a referral center for patients transferred from other hospitals. Criteria for identifying such referral centers are set forth in § 412.96.

(d) *Christian Science Sanatoria.* HCFA will adjust the prospective payment rates determined under Subpart D or E of this part if a hospital is a Christian Science sanatorium. Such a sanatorium's prospective payment rates will be determined in accordance with § 412.98.

(e) *Kidney acquisition costs incurred by hospitals approved as renal transplantation centers.* HCFA will pay for kidney acquisition costs incurred by renal transplantation centers on a reasonable cost basis. The criteria for this special payment provision are set forth in § 412.100.

(f) *Hospitals that are located in urban areas and that are reclassified as rural.* HCFA will adjust the rural Federal payment amounts for hospitals reclassified as rural, as defined in § 412.62(f). The criteria for this adjustment are set forth in § 412.102.

(g) *Hospitals that have a high percentage of ESRD beneficiary discharges.* HCFA will make an additional payment to a hospital if ten percent or more of its total Medicare discharges in a cost reporting period beginning on or after October 1, 1984 are ESRD beneficiary discharges. In determining ESRD discharges, discharges in DRG Nos. 302, 316 and 317 are excluded. The criteria for this additional payment are set forth in § 412.104.

(h) *Hospitals that serve a disproportionate share of low-income patients.* For discharges occurring on or after May 1, 1986 and before October 1, 1990, HCFA makes an additional payment to hospitals that serve a disproportionate share of low-income patients. The criteria for this additional payment are set forth in § 412.106.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16788, May 6, 1986; 53 FR 38529, Sept. 30, 1988]

§ 412.92 Special treatment: Sole community hospitals.

(a) *Criteria for classification as a sole community hospital.* HCFA classifies a hospital as a sole community hospital if it is located in a rural area (as defined in § 412.62(f), and meets one of the following conditions:

(1) The hospital is located more than 50 miles from other like hospitals.

(2) The hospital is located between 25 and 50 miles from other like hospitals and meets one of the following criteria:

(i) No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 50-mile radius of the hospital, or, if larger, within its service area;

(ii) The hospital has fewer than 50 beds and the intermediary certifies that the hospital would have met the criteria in paragraph (a)(2)(i) of this section were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital; or

(iii) Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least one month out of each year.

(3) The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least one month out of each year.

(b) *Classification procedures*—(1) *Request for classification as sole community hospital.* (i) The hospital must make its request to its fiscal intermediary.

(ii) If a hospital is seeking sole community hospital classification under paragraph (a)(2)(i) or (a)(2)(ii) of this section, the hospital must include the following information with its request:

(A) The hospital must provide patient origin data (for example, the number of patients from each zip code from which the hospital draws inpatients) for all inpatient discharges to document the boundaries of its service area.

(B) The hospital must provide patient origin data from all other hospitals located within a 50 mile radius of it or, if larger, within its service area, to document that no more than 25 percent of either all of the population or the Medicare beneficiaries residing in the hospital's service area and hospitalized for inpatient care were admitted to other like hospitals for care.

(iii) (A) If the hospital is unable to obtain the information required under paragraph (b)(1)(ii)(A) of this section concerning the residences of Medicare beneficiaries who were inpatients in other hospitals located within a 50 mile radius of the hospital or, if larger, within the hospital's service area, the hospital may request that HCFA provide this information.

(B) If a hospital obtains the information as requested under paragraph (b)(1)(iii)(A) of this section, that information is used by both the intermediary and HCFA in making the determination of the residences of Medicare beneficiaries under paragraphs (b)(1)(iii) and (b)(1)(iv) of this section, regardless of any other information concerning the residences of Medicare beneficiaries submitted by the hospital.

(iv) The intermediary will review the request and send the request, with its recommendation, to HCFA.

(v) HCFA will review the request and the intermediary's recommendation and forward its approval or disapproval to the intermediary.

(2) *Effective dates of classification.* (i) Sole community hospital status is effective 30 days after the date of HCFA's written notification of approval to the provider.

(ii) When a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses an HCFA denial of sole community hospital status and no further appeal is made, the sole community hospital status is effective as follows:

(A) If the hospital's application was submitted prior to October 1, 1983, its status as a sole community hospital is effective at the start of the cost reporting period for which it sought exemption from the cost limits.

(B) If the hospital's application for sole community hospital status was filed on or after October 1, 1983, the effective date is 30 days after the date of HCFA's original written notification of denial.

(iii) When a hospital is granted retroactive approval of sole community hospital status by a court order or a PRRB decision and the hospital wishes its sole community hospital status terminated before the date of the court order or PRRB determination, it must submit written notice to the HCFA regional office within 90 days of the court order or PRRB decision. A written request received after the 90-day period is effective no later than 30 days after the request is submitted.

(iv) A hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after 30 days after the date of HCFA's approval of the classification.

(3) *Duration of classification.* An approved classification as a sole community hospital will remain in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved.

(4) *Cancellation of classification.* (i) A hospital may at any time request cancellation of its classification as a sole community hospital, and be paid at rates determined under Subparts D and E of this part, as appropriate.

(ii) The cancellation becomes effective no later than 30 days after the date the hospital submits its request.

(iii) If a hospital requests that its sole community hospital classification be cancelled, it may not apply later for reclassification as a sole community hospital unless all hospitals within 50 miles of the facility have closed.

(5) *Automatic classification as a sole community hospital.* A hospital that has been granted an exemption from the hospital cost limits under § 413.30(e)(1) of this chapter before October 1, 1983, or whose request for the exemption was received by the appropriate intermediary before October 1, 1983, and was subsequently approved, will be automatically classified as a sole community hospital unless that classification has been cancelled under paragraph (b)(3) of this section, or there is a change in the circumstances under which the classification was approved.

(c) *Terminology.* As used in this section—

(1) The term "*miles*" means the shortest distance in miles measured over improved roads. An improved road for this purpose is any road which is maintained by a local, State, or Federal government entity and which is available for use by the general public.

(2) The term "*like hospital*" means a hospital furnishing short-term, acute care. HCFA will not evaluate comparability of specialty services in making determinations on classifications as sole community hospitals.

(3) The term "*service area*" means the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital.

(d) *Determining prospective payments rates for sole community hospitals*—(1) *General rule.* For all cost reporting periods beginning on or after October 1, 1983, the prospective payment rates for sole community hospitals equal 75 percent of the hospital-specific base payment rate (as determined under § 412.73) plus 25 percent of the appropriate regional prospective payment rate (as determined under Subpart D of this part).

(2) *Adjustments to payments.* A sole community hospital may receive an adjustment to its payments to take into account a significant decrease in number of discharges or a significant increase in inpatient operating costs, as described in paragraphs (e) and (f) of this section respectively.

(e) *Additional payments to sole community hospitals experiencing a significant volume decrease.* (1) For cost reporting periods beginning on or after October 1, 1983 and before October 1, 1990, HCFA provides for a payment adjustment for a sole community hospital for any cost reporting period during which the hospital experiences, due to circumstances as described in paragraph (e)(2) of this section a more than five percent decrease in its total discharges of inpatients as compared to its immediately preceding cost reporting period. If either the cost reporting period in question or the immediately preceding cost reporting period is other than a 12-month cost reporting period, the intermediary must convert the discharges to a monthly figure and multiply this figure by 12 to estimate the total number of discharges for a 12-month cost reporting period.

(2) To qualify for a payment adjustment on the basis of a decrease in discharges, a sole community hospital must submit its request no later than 180 days after the date on the intermediary's Notice of Amount of Program Reimbursement—

(i) Submit to the intermediary documentation demonstrating the size of the decrease in discharges, and the resulting effect on per discharge costs; and

(ii) Show that the decrease is due to circumstances beyond the hospital's control.

(3) HCFA determines a lump sum adjustment amount not to exceed the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue based on DRG-adjusted prospective payment rates (including outlier payments determined under Subpart F of this part and additional payments made for hospitals that serve a disproportionate share of low-income patients as determined under § 412.106 and for indirect medical education costs as determined under § 412.118).

(i) The individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies;

(A) In determining the adjustment amount, HCFA considers—

(B) The hospital's fixed (and semifixed) costs, other than those costs reimbursed on a reasonable cost basis under Part 413 of this chapter; and

(C) The length of time the hospital has experienced a decrease in utilization.

(ii) HCFA makes its determination within 180 days from the date HCFA receives from the intermediary the hospital's request and all other necessary information.

(iii) The HCFA determination is subject to review under Subpart R of Part 405 of this chapter.

(f) *Additional payments to other hospitals experiencing a significant volume decrease.* (1) For cost reporting periods beginning on or after October 1, 1987 and before October 1, 1990, HCFA provides for a payment adjustment for a hospital that qualifies as a sole community hospital but is not receiving payment as a sole community hospital under paragraph (d) of this section for any cost reporting period during which the hospital experiences, due to circumstances beyond its hospital's control, a decrease of more than five percent in its total discharges of inpatients as compared to its immediately preceding cost reporting period. If either the cost reporting period in question or the immediately preceding cost reporting period is other than a 12-month cost reporting period, the intermediary must convert the discharges to a monthly figure and multiply that figure by 12 to estimate the total number of discharges for a 12-month cost reporting period. The payment adjustment is determined under the provisions of paragraph (e)(3) of this section.

(2) To qualify for a payment adjustment under paragraph (f)(1) of this section, a hospital must complete the following:

(i) No later than 180 days from the date of the intermediary's Notice of Amount of Program Reimbursement, the hospital must submit to the HCFA regional office a request for sole community hospital status for the purpose of the payment adjustment only furnishing the documentation as may be necessary to demonstrate that the hospital meets the criteria in paragraph (a) of this section.

(ii) Within 180 days from the date on the notice from the regional office indicating that sole community hospital status has been granted for purposes of the payment adjustment only, the hospital submits to the intermediary documentation demonstrating the size of the decrease in discharges and the resulting effect on per discharge costs and shows that the decrease is due to circumstances beyond the hospital's control.

(g) *Payment adjustment for new inpatient facilities or services*—(1) *General rule.* If a sole community hospital experiences a significant increase in inpatient operating costs resulting from new inpatient services or facilities that were not available in the hospital during its base period and that are necessary for patient care, HCFA may adjust payments made to the hospital to ensure that it is receiving reasonable compensation, as defined in paragraph (g)(2) of this section, for the operating costs of the new inpatient facilities or services (including special care units).

(2) *Definitions.* For purposes of this paragraph—"Reasonable compensation" means that a sole community hospital's total DRG revenue based on DRG-adjusted prospective payment rates (including outlier payments determined under Subpart F of this part, and additional payments made for hospitals that serve a disproportionate share of low-income patients as determined under § 412.106 and for indirect medical education costs as determined under § 412.118) are equal to or greater than its Medicare inpatient operating costs as defined under § 412.2(c).

(3) *Documentation.* To qualify for an adjustment to its payments, a sole community hospital must submit documentation, including any additional cost information requested by HCFA within 180 days after a final notice of program reimbursement, to its intermediary to—

(i) Identify the new inpatient facilities or services responsible for the increase in inpatient operating costs, and the dates that the facilities or services became operational;

(ii) Specify the direct costs of the new inpatient facilities or services and their impact on Medicare payments; and

(iii) Specify the indirect costs attributable to the new inpatient facilities or services that are not already reflected in the Medicare payments received by the hospital.

(4) *Intermediary recommendation.* The intermediary forwards the following material to HCFA within 60 days of receipt from the hospital:

(i) The hospital's documentation and the intermediary's verification thereof;

(ii) Its analysis and recommendation; and

(iii) The hospital's Medicare cost reports for the years in which the increase in costs occurred and the prior year.

(5) *Determination by HCFA.* HCFA determines, within 120 days of receiving all the necessary information from the intermediary, whether an adjustment to the payment amounts is warranted based on, but not limited to—

(i) A complete analysis of the documentation submitted;

(ii) A comparison of the costs and utilization of the new inpatient facility or service to the costs and utilization of a similar facility or service in a similar hospital or hospitals;

(iii) An evaluation of the change in the hospital's financial position from the cost reporting period immediately prior to the addition of the new inpatient service or facility to the cost reporting period when the new service or facility initially became operational;

(iv) A determination that the hospital's Medicare inpatient operating costs exceed its Medicare inpatient operating payments; and

(v) A determination of reasonable compensation equal to the lesser of the hospital's—

(A) Medicare inpatient operating loss attributable to the added services or facilities; or

(B) Total Medicare inpatient operating loss.

(6) *Affected cost reporting periods.* Adjustments that are authorized by HCFA under this paragraph or that are based on an administrative decision (§§ 405.1871 and 405.1875 of this chapter) or a judicial review decision (§ 405.1877 of this chapter) that is no longer subject to review by a higher reviewing authority, are effective for the cost reporting period in which the new services or facilities were added, and for later cost reporting periods, as

necessary, beginning before October 1, 1989.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 31496, Sept. 3, 1986; 51 FR 34793, Sept. 30, 1986; 52 FR 30367, Aug. 14, 1987; 52 FR 33057, Sept. 1, 1987; 53 FR 38529, Sept. 30, 1988]

§ 412.94 Special treatment: Cancer hospitals.

(a) *Criteria for classification as a cancer hospital.* HCFA classifies a hospital as a cancer hospital only if the hospital—

(1) Was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983;

(2) Demonstrates that the entire facility is organized primarily for treatment of and research on cancer (that is, the facility is not a subunit of an acute general hospital or university-based medical center); and

(3) Shows that at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease. (The principal diagnosis for this purpose is defined as the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital. For the purposes of meeting this definition, only discharges with ICD-9-CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect neoplastic disease.)

(b) *Payment.* (1) A hospital meeting the criteria in paragraph (a) of this section may elect, during its first cost reporting period subject to the prospective payment system, to be reimbursed on a reasonable cost basis under Part 413 of this chapter, subject to the rate of increase limit under § 413.40 of this chapter.

(2) If the hospital elects reasonable cost reimbursement, it will continue to be reimbursed on that basis until it elects to enter the prospective payment system.

(3) A hospital that does not elect reasonable cost reimbursement before the end of its first cost reporting period subject to prospective payment, or that elects to enter the prospective payment system, may not again apply for an adjustment under this section.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986]

§ 412.96 Special treatment: Referral centers.

(a) *Criteria for classification as a referral center: Basic rule.* HCFA classifies a hospital as a referral center only if the hospital is a Medicare participating acute care hospital and meets the applicable criteria of paragraph (b) or (c) of this section.

(b) *Criteria for cost reporting periods beginning on or after October 1, 1983.* The hospital meets either of the following criteria:

(1) The hospital is located in a rural area (as defined in § 412.63(b)) and has the following number of beds, as determined under the provisions of § 412.118(b), available for use:

(i) Effective for discharges occurring before April 1, 1988, the hospital has 500 or more beds.

(ii) Effective for discharges occurring on or after April 1, 1988, the hospital has 25 or more beds during its most recently completed cost reporting period unless the hospital submits written documentation with its application that its bed count has changed since the close of its most recently completed cost reporting period for one or more of the following reasons:

(A) Merger of two or more hospitals.

(B) Reopening of acute care beds previously closed for renovation.

(C) Transfer to the prospective payment system of acute care beds previously classified as part of an excluded unit.

(D) Expansion of acute care beds available for use and permanently maintained for lodging inpatients, excluding beds in corridors and other temporary beds.

(2) The hospital shows that—(i) At least 50 percent of its Medicare patients are referred from other hospitals or from physicians not on the staff of the hospital; and (ii) At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital, and at least 60 percent of all the services that the hospital furnishes to Medicare beneficiaries are

furnished to beneficiaries who live more than 25 miles from the hospital.

(c) *Alternative criteria.* For cost reporting periods beginning on or after October 1, 1985, a hospital that does not meet the criteria of paragraph (b) of this section is classified as a referral center if it is located in a rural area (as defined in § 412.62(f)) and meets the criteria specified in paragraphs (c)(1) and (c)(2) of this section and at least one of the three criteria specified in paragraphs (c)(3), (c)(4), and (c)(5) of this section.

(1) *Case-mix index.* HCFA sets forth national and regional case-mix index values in each year's annual notice of prospective payment rates published under § 412.8(b). The methodology HCFA uses to calculate these criteria is described in paragraph (g) of this section. The case-mix index value to be used for an individual hospital in the determination of whether it meets the case-mix index criteria is that calculated by HCFA from the hospital's own billing records for Medicare discharges as processed by the fiscal intermediary and submitted to HCFA. The hospital's case-mix index for discharges (not including discharges from distinct part units excluded from the prospective payment system under Subpart B of this part) during the Federal fiscal year that ended one year prior to the beginning of the cost reporting period for which the hospital is seeking referral center status must be at least equal to—

(i) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1985 and before October 1, 1986, the national or regional case-mix index value; or

(ii) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1986, the national case-mix index value as established by HCFA or the median case-mix index value for urban hospitals located in each region. In calculating the median case-mix index for each region, HCFA excludes the case-mix indexes of hospitals receiving indirect medical education payments as provided in § 412.118.

(2) *Number of discharges.* (i) HCFA sets forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates published under § 412.8(b). The methodology HCFA uses to calculate these criteria is described in paragraph (h) of this section. Except as provided in paragraph (c)(2)(ii) of this section for an osteopathic hospital, for the hospital's most recently completed cost reporting period, its number of discharges (not including discharges from distinct part units excluded from the prospective payment system under Subpart B of this part or from newborn units) is at least equal to—

(A) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1985 and before October 1, 1986, the number of discharges under either the national or regional criterion; or

(B) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1986, 5,000 discharges or, if less, the median number of discharges for urban hospitals located in each region.

(ii) For cost reporting periods beginning on or after January 1, 1986, an osteopathic hospital, recognized by the American Osteopathic Hospital Association, that is located in a rural area must have at least 3,000 discharges during its most recently completed cost reporting period to meet the number of discharges criterion. The 3,000 discharges benchmark is also used in evaluating an osteopathic hospital for purposes of the triennial review.

(3) *Medical staff.* More than 50 percent of the hospital's active medical staff are specialists who meet one of the following conditions:

(i) Are certified as specialists by one of the Member Boards of the American Board of Medical Specialties or the Advisory Board of Osteopathic Specialists.

(ii) Have completed the current training requirements for admission to the certification examination of one of the Member Boards of the American Board of Medical Specialties or the Advisory Board of Osteopathic Specialists.

(iii) Have successfully completed a residency program in a medical specialty accredited by the Accreditation

Council of Graduate Medical Education or the American Osteopathic Association.

(4) *Source of inpatients.* At least 60 percent of all its discharges are for inpatients who reside more than 25 miles from the hospital.

(5) *Volume of referrals.* At least 40 percent of all inpatients treated at the hospital are referred from other hospitals or from physicians not on the hospital's staff.

(d) *Payment to rural referral centers.* Effective for discharges occurring on or after April 1, 1988, a hospital that is located in a rural area and meets the criteria of paragraphs (b)(1), (b)(2) or (c) of this section is paid prospective payments per discharge based on the applicable other urban payment rates as determined in accordance with § 412.63, as adjusted by the hospital's area wage index.

(e) [Reserved]

(f) *HCFA review of referral center status.* The status of each hospital that is receiving a referral center adjustment will be reviewed by the HCFA regional office every three years to determine if the hospital continues to meet applicable criteria. To retain referral center status, a hospital must meet the applicable criteria in at least two of the three years. If the determination is to the effect that the hospital no longer qualifies for a referral center adjustment, HCFA will discontinue the adjustment beginning on the first day of the hospital's next cost reporting period.

(g) *Methodology for calculating case-mix index criteria.* HCFA calculates the national and regional case-mix index value criteria as described in paragraphs (g)(1) through (g)(4) of this section.

(1) *Updating process.* HCFA updates the national and regional case-mix index standards using the latest available data from hospitals subject to the prospective payment system for the Federal fiscal year.

(2) *Source of data.* In making the calculations described in paragraph (g)(1) of this section, HCFA uses all inpatient hospital bills received for discharges subject to prospective payment during the Federal fiscal year being monitored.

(3) *Effective date.* HCFA sets forth the national and regional criteria in the annual notice of prospective payment rates published under § 412.8(b). These criteria are used to determine if a hospital qualifies for referral center status for cost reporting periods beginning on or after October 1 of the Federal fiscal year to which the notice applies.

(4) *Applicability of criteria to HCFA review of referral center status.* For purposes of the triennial HCFA review of a referral center's status as described in paragraph (f) of this section, the referral center's case-mix index value for a Federal fiscal year is evaluated using the appropriate case-mix value criteria published in the annual notice of prospective payment rates.

(h) *Methodology for calculating number of discharges criteria.* For purposes of determining compliance with the national or regional number of discharges criterion under paragraph (c)(2) of this section, HCFA calculates the criteria as follows:

(1) *Updating process.* HCFA updates the national and regional number of discharges using the latest available data for levels of admissions or discharges or both.

(2) *Source of data.* In making the calculations described in paragraph (h)(1) of this section, HCFA uses the most recent hospital admissions or discharge data available.

(3) *Annual notice.* HCFA sets forth the national and regional criteria in the annual notice of prospective payment rates published under § 412.8(b). These criteria are compared to an applying hospital's number of discharges for its most recently completed cost reporting period in determining if the hospital qualifies for referral center status for cost reporting periods beginning on or after October 1 of the Federal fiscal year to which the notice applies.

(4) *Applicability of criteria to HCFA review of referral center status.* For purposes of the triennial review of a referral center's status as described in paragraph (f) of this section, the referral center's number of discharges for its most recently completed cost reporting period is evaluated using the

appropriate discharge criteria published in the annual notice of prospective payment rates.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 51 FR 31496, Sept. 3, 1986; 51 FR 34980, Oct. 1, 1986; 51 FR 42234, Nov. 24, 1986; 52 FR 33058, Sept. 1, 1987; 53 FR 38531, Sept. 30, 1988]

§ 412.98 Special treatment: Christian Science Sanatoria.

(a) *General rule.* If a Christian Science Sanatorium is not excluded from the prospective payment system under Subpart B of this part, HCFA will pay, for inpatient hospital services furnished to a beneficiary by that sanatorium, a predetermined fixed amount per discharge based on the sanatorium's historical inpatient operating costs per discharge.

(b) *Prospective payment rates.* For cost reporting periods beginning on or after October 1, 1983, the sanatorium's prospective payment rate will be equal to the amount that would constitute the sanatorium's target amount under § 413.40(c)(4) of this chapter if the institution were subject to the rate of increase ceiling specified in § 413.40 of this chapter instead of the prospective payment system. This amount will not be adjusted for the DRG weighting factor.

(c) *Outlier payments.* A Christian Science sanatorium is not eligible for outlier payments under Subpart F of this part.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986]

§ 412.100 Special treatment: Renal transplantation centers.

(a) *Adjustments for renal transplantation centers.*

(1) HCFA will adjust the prospective payment rates determined under Subparts D and E of this part for hospitals approved as renal transplantation centers (described at §§ 405.2170 and 405.2171 of this chapter) to remove the estimated net expenses associated with kidney acquisition.

(2) Kidney acquisition costs will be treated apart from the prospective payment rate and reimbursement to the hospital will be adjusted in each reporting period to reflect an amount necessary to compensate the hospital for reasonable expenses of kidney acquisition.

(b) *Costs of kidney acquisition.* Expenses recognized under this section include costs of acquiring a kidney, from a live donor or a cadaver, irrespective of whether the kidney was obtained by the hospital or through an organ procurement agency. These costs include—

(1) Tissue typing, including tissue typing furnished by independent laboratories;

(2) Donor and recipient evaluation;

(3) Other costs associated with excising kidneys, such as donor general routine and special care services;

(4) Operating room and other inpatient ancillary services applicable to the donor;

(5) Preservation and perfusion costs;

(6) Charges for registration of recipient with a kidney transplant registry;

(7) Surgeons' fees for excising cadaver kidneys;

(8) Transportation;

(9) Costs of kidneys acquired from other providers or kidney procurement organizations;

(10) Hospital costs normally classified as outpatient costs applicable to kidney excisions (services include donor and donee tissue typing, work-up, and related services furnished prior to admission);

(11) Costs of services applicable to kidney excisions which are rendered by residents and interns not in approved teaching programs; and

(12) All pre-admission physicians services, such as laboratory, electroencephalography, and surgeon fees for cadaver excisions, applicable to kidney excisions including the costs of physicians services.

§ 412.102 Special treatment: Hospitals reclassified as rural.

Effective with cost reporting periods beginning or or after October 1, 1983, a hospital reclassified as rural, as defined in § 412.62(f), may receive an adjustment to its rural Federal payment amount for two successive cost reporting periods.

(a) *First year adjustment.* The hospital will have its rural average standardized amounts adjusted on the basis of an additional amount that equals two-thirds of the difference between the urban and rural standardized amounts reflecting the appropriate regional/national blend otherwise applicable to the cost reporting period for which the adjustment is made.

(b) *Second year adjustment.* If a hospital continues to be reclassified as rural, it will have its rural average standardized amounts adjusted on the basis of an additional amount that equals one-third of the difference between the urban and rural amounts reflecting the appropriate regional/national blend applicable to the cost reporting period for which the adjustment is made.

§ 412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

(a) *Criteria for classification.* Effective with cost reporting periods that begin on or after October 1, 1984, HCFA will provide an additional payment to a hospital for inpatient dialysis provided to ESRD beneficiaries if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into DRG No. 302 (Kidney Transplant), DRG No. 316 (Renal Failure) or DRG No. 317 (Admit for Renal Dialysis), constitute ten percent or more of its total Medicare discharges.

(b) *Additional payment.* A hospital that meets the criteria of paragraph (a) of this section will be paid an additional payment for each ESRD beneficiary discharge except those excluded under paragraph (a) of this section.

(1) The payment is based on the estimated weekly cost of dialysis and the average length of stay of ESRD beneficiaries for the hospital.

(2) The estimated weekly cost of dialysis is the average number of dialysis sessions furnished per week during the 12-month period that ended June 30, 1983 multiplied by the average cost of dialysis for the same period.

(3) The average cost of dialysis includes only those costs determined to be directly related to the dialysis service. (These costs include salary, employee health and welfare, drugs, supplies, and laboratory services.)

(4) The average cost of dialysis will be reviewed and adjusted, if appropriate, at the time the composite rate reimbursement for outpatient dialysis is reviewed.

(5) The payment to a hospital will be equal to the average length of stay of ESRD beneficiaries in the hospital, expressed as a ratio to one week, times the estimated weekly cost of dialysis multiplied by the number of ESRD beneficiary discharges except for those excluded under paragraph (a) of this section. This payment is made only on the Federal portion of the payment rate.

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

(a) *Basic rule.* (1) Unless a hospital elects the option concerning the period of time used for counting the number of patient days (that is, the hospital's cost reporting period rather than the Federal fiscal year), as described in paragraph (a)(2) of this section, a hospital's disproportionate patient percentage is the sum of the following, expressed as a percentage:

(i) Number of covered patient days associated with discharges occurring during each month of the Federal fiscal year in which the hospital's cost reporting period begins of those patients who are entitled during that month to both Medicare Part A and Supplemental Security Income benefits under title XVI of the Act (excluding those patients receiving State supplementation only), summed for the months of the Federal fiscal year, and divided by the number of patient days associated with discharges occurring during that same Federal fiscal year of those patients entitled to Medicare Part A.

(ii) Number of patient days during the hospital's cost reporting period of those patients who are entitled to Medicaid but not to Medicare Part A divided by the total number of patient days in that same period.

(2) For purposes of making the calculation in paragraph (a)(1)(i) of this section, a hospital may elect to have the count of the number of patient days made on the basis of covered pa-

tient days associated with discharges occurring during each month of its cost reporting period, rather than by Federal fiscal year, if the hospital furnishes to its intermediary, in machine-readable tape format as prescribed by HCFA, data on its Medicare Part A patients for its cost reporting period.

(3) The number of beds in a hospital is determined as specified in § 412.118(b).

(4) The definitions for urban and rural areas are the same as those set forth in § 412.62(f).

(5) For purposes of making the calculation in paragraph (a)(1) of this section, patient days are determined by counting those days attributable only to areas of the hospital subject to the prospective payment system. Patient days attributable to areas or units of the hospital excluded from the prospective payment system are not included in the count of patient days.

(b) *Criteria for classification*—(1) *General rule.* For discharges occurring on or after May 1, 1986 and before October 1, 1990, a payment adjustment (as described in paragraph (c) of this section) is made for each hospital that meets one of the following criteria:

(i) During the hospital's cost reporting period, the hospital has a disproportionate patient percentage that is at least equal to—

(A) 15 percent, if the hospital is located in an urban area and has 100 or more beds;

(B) 40 percent, if the hospital is located in an urban area and has fewer than 100 beds; or

(C) 45 percent, if the hospital is located in a rural area.

(ii) The hospital is located in an urban area, has 100 or more beds, and can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for indigent care furnished to patients who are not covered by Medicare or Medicaid.

(2) *Special rule for certain rural hospitals.* For discharges occurring on or after October 1, 1986 and before October 1, 1990, a payment adjustment (as described in paragraph (c) of this section) is made for each hospital that, during its cost reporting period, has a disproportionate patient percentage that is at least equal to 15 percent, if the hospital is located in a rural area and has 500 or more beds.

(c) *Payment adjustment.* For discharges occurring on or after October 1, 1988, if a hospial meets one of the criteria in paragraph (b) of this section, the hospital's total DRG revenue based on DRG-adjusted prospective payment rates (for transition period payments, the Federal portion of the hospital's payment rates), including outlier payments determined under Subpart F of this part but excluding additional payments made under the provisions of this subpart or § 412.118, is increased by the disproportionate share payment adjustment factor, determined as follows:

(1) If the hospital meets the criteria of paragraph (b)(1)(i)(A) or (b)(2) of this section, the disproportionate share payment adjustment factor is 2.5 percent plus one-half the difference between the hospital's disproportionate patient percentage and 15 percent.

(2) If the hospital meets the criteria of paragraph (b)(1)(i)(B) of this section, the disproportionate share payment adjustment factor is five percent.

(3) If the hospital meets the criteria of paragraph (b)(1)(i)(C) of this section, the disproportionate share payment adjustment factor is four percent.

(4) If the hospital meets the criteria of paragraph (b)(1)(ii) of this section, the disproportionate share payment adjustment factor is 25 percent.

[51 FR 16788, May 6, 1986, as amended at 51 FR 31497, Sept. 3, 1986; 52 FR 23834, June 25, 1987; 53 FR 38531, Sept. 30, 1988]

Subpart H—Payments to Hospitals under the Prospective Payment System

§ 412.110 Total Medicare payment.

Under the prospective payment system, Medicare's total payment for inpatient hospital services furnished to a Medicare beneficiary by a hospital will equal the sum of the payments listed in §§ 412.112 through 412.115, reduced by the amounts specified in § 412.120.

§ 412.112 Payments determined on a per case basis.

A hospital will be paid on a per case basis the following amounts:

(a) The appropriate prospective payment rate for each discharge as determined in accordance with Subparts D, E, and G of this part.

(b) The appropriate outlier payment amounts determined under Subpart F of this part.

§ 412.113 Payments determined on a reasonable cost basis.

(a) *Capital related costs.* (1) *Payment.* Subject to the reductions described in paragraph (a)(2) of this section, payment for capital-related costs (as described in § 413.130 of this chapter) is determined on a reasonable cost basis.

(2) *Reduction to capital-related payments.* (i) Except for sole community hospitals as defined in § 412.92, the amount of capital-related payments (including a return on equity capital as provided under § 413.157 of this chapter) is reduced by—

(A) Three and one-half percent for payments attributable to portions of cost reporting periods occurring during Federal FY 1987;

(B) Seven percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during Federal FY 1988; and

(C) Ten percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during Federal FY 1989.

(ii) If a hospital's cost reporting period encompasses more than one Federal fiscal year, the reductions to capital-related payments are determined on a prorated monthly basis.

(b) *Direct medical education costs.* Payment for the cost of approved medical educational activities as defined in § 413.85 of this chapter is made on a reasonable cost basis (except with respect to activities defined in § 413.85(d) of this chapter). For cost reporting periods beginning on or after July 1, 1985, but before July 1, 1986, payment for these reasonable costs is limited as described in § 413.85(a) of this chapter.

(c) *Anesthesia services of hospital-employed nonphysician anesthetists.* For cost reporting periods beginning on or after October 1, 1984 through any part of a cost reporting period occurring before January 1, 1989, payment will be determined on a reasonable cost basis for anesthesia services provided in the hospital by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiology assistants) employed by the hospital or obtained under arrangements.

(d) *Kidney acquisition costs incurred by hospitals with approved renal transplantation centers.* Payment for kidney acquisition costs incurred by hospitals with approved renal transplantation centers, as described in § 412.100, is made on a reasonable cost basis.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 31497, Sept. 3, 1986; 51 FR 34980, Oct. 1, 1986; 52 FR 33058, Sept. 1, 1987; 52 FR 35350, Sept. 18, 1987; 53 FR 1627, Jan. 21, 1988; 53 FR 38532, Sept. 30, 1988]

§ 412.115 Additional payments.

(a) *Bad debts.* An additional payment will be made to each hospital in accordance with § 413.80 of this chapter for bad debts attributable to deductible and coinsurance amounts related to covered services received by beneficiaries.

(b) *Indirect medical education costs.* An additional payment may be made to a hospital for indirect medical education costs attributable to an approved graduate medical education. Indirect medical education costs are determined in accordance with § 412.118.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986]

§ 412.116 Method of payment.

(a) *General rule.* Unless the provisions of paragraphs (b) and (c) of this section apply, hospitals are paid for each discharge based on the submission of a discharge bill. Payments for inpatient hospital services furnished by an excluded distinct part psychiatric or a rehabilitation unit of a hospital are made as described in § 413.64 (a), (c), (d), and (e) of this chapter.

(b) *Periodic interim payments*—(1) *Criteria for receiving periodic interim payments.* Effective with claims received on or after July 1, 1987, a hospital that meets the criteria in § 413.64(h) of this chapter may request in writing to receive periodic interim payments as described in this paragraph. A hospital that is receiving periodic interim payments also receives payment on this basis for inpatient hospital services furnished by its excluded distinct part psychiatric or rehabilitation unit.

(i) *Failure of intermediary to make prompt payment.* Beginning with claims received in April 1987, the hospital's fiscal intermediary does not meet the requirements of section 1816(c)(2) of the Act, which provides for prompt payment of claims under Medicare Part A, for three consecutive calendar months. The hospital may continue to receive periodic interim payments until the intermediary meets the requirements of section 1816 (c)(2) of the Act for three consecutive calendar months. For purposes of this paragraph, a hospital that is receiving periodic interim payments as of June 30, 1987 and meets the requirements of § 413.64(h) of this chapter may continue to receive payment on this basis until the hospital's intermediary meets the requirements of section 1816(c)(2) of the Act for three consecutive calendar months beginning with April 1987.

(ii) *Hospitals that serve a disproportionate share of low-income patients.* The hospital is receiving periodic interim payments as of June 30, 1987 and has a disproportionate share payment adjustment factor of at least 5.1 percent as determined under § 412.106(c) for purposes of establishing the average standardized amounts for discharges occurring on or after October 1, 1986 and before October 1, 1987. The hospital's request must be made by a date prior to July 1, 1987, specified by the intermediary.

(iii) *Small rural hospitals.* The hospital is receiving periodic interim payments as of June 30, 1987, makes its request by a date prior to July 1, 1987, specified by the intermediary, and, on July 1, 1987, the hospital—

(A) Is located in a rural area as defined in § 412.62(f); and

(B) Has 100 or fewer beds available for use.

(2) *Frequency of payment.* The intermediary estimates a hospital's prospective payments as described in paragraph (b)(3) of this section and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. Each payment is made two weeks after the end of a biweekly period of service, as described in § 413.64(h)(5) of this chapter. These payments are subject to final settlement.

(3) *Amount of payment.* (i) The biweekly interim payment amount is based on the total estimated Medicare discharges for the reporting period multiplied by the hospital's estimated average prospective payment amount as described in paragraph (b)(3)(ii) of this paragraph. These interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a hospital receives interim payments for less than a full reporting period.

(ii) For purposes of determining periodic interim payments under this paragraph, a hospital's estimated average prospective payment amount is computed as follows:

(A) If a hospital has no payment experience under the prospective payment system, the intermediary computes the hospital's estimated average prospective payment amount by multiplying its payment rates as determined under § 412.70(c), but without adjustment by a DRG weighting factor, by the hospital's case-mix index, and subtracting from this amount estimated deductibles and coinsurance.

(B) If a hospital has payment experience under the prospective payment system, the intermediary computes a hospital's estimated average prospective payment amount based on that payment experience, adjusted for projected changes, and subtracts from this amount estimated deductibles and coinsurance.

(4) *Termination of periodic interim payments*—(i) *Request by the hospital*

A hospital receiving periodic interim payments may convert to payments on a per discharge basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates periodic interim payments if—

(A) A hospital no longer meets the requirements of § 413.64(h);

(B) A hospital is receiving payment under the criterion in paragraph (b)(1)(i) of this section and the intermediary meets the prompt payment requirements of section 1816(c)(2) of the Act for three consecutive calendar months; or

(C) A hospital that is receiving payment under the criterion set forth in paragraph (b)(1)(iii) of this section no longer meets the criterion.

(iii) *Limitation on reelection.* If a hospital that is receiving periodic interim payments under the criterion set forth in paragraph (b)(1)(ii) or (b)(1)(iii) of this section is removed from that method of payment either by its own request or by the intermediary, it may reelect to receive periodic interim payments only under the criterion set forth in paragraph (b)(1)(i) of this section.

(c) *Special interim payments for certain costs.* For capital-related costs and the direct costs of medical education, which are not included in prospective payments but are reimbursed as specified in §§ 413.130 and 413.85 of this chapter, respectively, interim payments are made subject to final cost settlement. Interim payments for capital-related items and the estimated cost of approved medical education programs (applicable to inpatient costs payable under Part A and for kidney acquisition costs in hospitals approved as renal transplantation centers) are determined by estimating the reimbursable amount for the year based on the previous year's experience and on substantiated information for the current year and divided into 26 equal biweekly payments. Each payment is made two weeks after the end of a biweekly period of services, as described in § 413.64(h)(5) of this chapter. The interim payments are reviewed by the intermediary at least twice during the reporting period and adjusted if necessary.

(d) *Outlier payments.* Payments for outlier cases (described in Subpart F of this part) are not made on an interim basis. The outlier payments are made based on submitted bills and represent final payment.

(e) *Accelerated payments*—(1) *General rule.* Upon request, an accelerated payment may be made to a hospital that is not receiving periodic interim payments under paragraph (b) of this section if the hospital is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the hospital.

(ii) Due to an exceptional situation, there is a temporary delay in the hospital's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* A hospital's request for an accelerated payment must be approved by the intermediary and HCFA.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as hospital bills are processed or by direct payment by the hospital.

[53 FR 1627, Jan. 21, 1988, as amended at 53 FR 38532, Sept. 30, 1988]

§ 412.118 Determination of indirect medical education adjustment.

To determine the indirect medical education costs, HCFA uses the following procedures:

(a) *Basic data.* HCFA determines the following for each hospital:

(1) The hospital's ratio of full-time equivalent interns and residents, except as limited under paragraph (g) of this section, to number of beds (as determined in paragraph (b) of this section).

(2) The hospital's total DRG revenue based on DRG-adjusted prospective payment rates (for transition period payments, the Federal portion of the hospital's payment rates), including outlier payments determined

under Subpart F of this part but excluding additional payments made under the provisions of Subpart G of this part. For cost reporting periods beginning on or after January 1, 1986, for purposes of this section, the total DRG revenue is not offset for payments made to outside suppliers under § 489.23 of this chapter for nonphysician services furnished to beneficiaries entitled to Medicare Part A.

(b) *Determination of number of beds.* For purposes of this section, the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period, not including beds assigned to newborns, custodial care, and excluded distinct part hospital units, and dividing that number by the number of days in the cost reporting period.

(c) *Measurement for teaching activity.* The factor representing the effect of teaching activity on inpatient operating costs is equal to the following:

(1) For discharges occurring on or after May 1, 1988 and before October 1, 1990, the factor equals .405.

(2) For discharges occurring on or after October 1, 1990, the factor equals .5795.

(d) *Determination of education adjustment factor.* (1) For discharges occurring on or after October 1, 1988 and before October 1, 1990, each hospital's education adjustment factor is calculated as follows:

(i) *Step one*—A factor representing the sum of 1.00 plus the hospital's ratio of full-time equivalent interns and residents to beds, as determined under paragraph (a)(1) of this section, is raised to an exponential power equal to the factor set forth in paragraph (c)(1) of this section.

(ii) *Step two*—The factor derived from step one is reduced by 1.00.

(iii) *Step three*—The factor derived from completing steps one and two is multiplied by 1.89.

(2) For discharges, occurring on or after October 1, 1990, each hospital's education adjustment factor is calculated as follows:

(i) *Step one*—A factor representing the sum of 1.00 plus the hospital's ratio of full-time equivalent interns and residents to beds, as determined under paragraph (a)(1) of this section, is raised to an exponential power equal to the factor set forth in paragraph (c)(2) of this section.

(ii) *Step two*—The factor derived from step one is reduced by 1.00.

(iii) *Step three*—The factor derived from completing steps one and two is multiplied by 1.43.

(e) *Determination of payment amount.* Each hospital's indirect medical education payment is determined by multiplying the total DRG revenue, as determined under paragraph (a)(2) of this section, by the applicable education adjustment factor derived in paragraph (d) of this section.

(f) *Count of interns and residents.* In order to have interns and residents included in the count under paragraph (a)(1) of this section, the following requirements must be met:

(1) The interns and residents must be enrolled in a teaching program approved under § 413.85 of this chapter (excluding those employed by the hospital, but furnishing services at another site).

(2) The hospital must submit an annual report to its fiscal intermediary. The report must include the following information:

(i) A listing, by specialty, of all interns and residents assigned to the hospital and providing services to the hospital on September 1 of that year. If September 1 falls on a weekend or a Federal holiday, the next business day is used for purposes of the count of interns and residents. For cost reporting periods beginning on or after October 1, 1984 and before July 1, 1985, the hospital must also report this information for April 15, 1985.

(ii) The social security number of each intern and resident.

(iii) The hospital unit or department to which each intern and resident is assigned on the day of the count.

(3) No intern or resident will be counted as more than one full-time employee on the date counted, regardless of the number of hospitals in which he or she is providing services.

(4) Fiscal intermediaries must verify the correct count of interns and residents and may review the hospital's entire cost reporting period.

(g) *Limits on count of interns and residents.* (1) Interns and residents who are assigned, to a setting other than the inpatient or outpatient department of the hospital (such as a freestanding family practice center or an excluded distinct part hospital unit) on the day that the count of interns and residents (as described in paragraph (f)(2)(i) of this section) is made are not counted as full-time equivalents. Only the percentage of time that these interns and residents spend in the portion of the hospital subject to the prospective payment system or in the outpatient department of the hospital on the day the count is made is used to determine the indirect medical education adjustment.

(2) Interns and residents in anesthesiology who are employed to replace anesthetists are not counted as full-time equivalents.

(h) *Intermediary review.* Based on its review of a hospital's documentation concerning the hospital's count of interns and residents under this section, the intermediary may adjust the intern and resident-to-bed ratio for purposes of the final indirect medical education payment.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35690, Sept. 3, 1985; 51 FR 16788, May 6, 1986; 51 FR 31497, Sept. 3, 1986; 51 FR 34793, Sept. 30, 1986; 52 FR 23834, June 25, 1987; 53 FR 38532, Sept. 30, 1988]

§ 412.120 Reductions to total payments.

(a) *Deductible and coinsurance.* Subject to paragraph (a)(2) of this section, the total Medicare payments otherwise payable to a hospital will be reduced by the applicable deductible and coinsurance amounts related to inpatient hospital services as determined in accordance with §§ 409.82, 409.83, and 409.87 of this chapter.

(b) *Payment by workers' compensation, automobile medical, no-fault or liability insurance or an employer group health plan primary to Medicare.* If workers' compensation, automobile medical, no-fault, or liability insurance or an employer group health plan which is primary to Medicare pays in full or in part, the Medicare payment will be determined in accordance with the following guidelines:

(1) If workers' compensation pays, in accordance with the applicable provisions of §§ 405.316 through 405.321 of this chapter.

(2) If automobile medical, no-fault, or liability insurance pays, in accordance with the applicable provisions of §§ 405.322 through 405.325 of this chapter.

(3) If an employer group health plan which is primary to Medicare pays for services to ESRD beneficiaries, in accordance with the applicable provisions of §§ 405.326 through 405.329 of this chapter.

(4) If an employer group health plan which is primary to Medicare pays for services to employees age 65-69 and their spouses age 65-69, in accordance with the applicable provisions of §§ 405.340 through 405.344 of this chapter.

(c) *Part B payment to outside suppliers.* HCFA will reduce payments for inpatient hospital services to take into account 100 percent of the reasonable charges (before application of Medicare Part B deductible and coinsurance amounts) for nonphysician services furnished, to beneficiaries entitled to benefits under Medicare Part A, by an outside supplier under § 489.23 of this chapter.

§ 412.125 Effect of change of ownership on payments under the prospective payment system.

When a hospital's ownership changes, as described in § 489.18 of this chapter, the following rules apply:

(a) Payment for the operating costs of inpatient hospital services for each patient, including outlier payments, as provided in § 412.112, and payments for indirect medical education costs as determined under § 412.118, will be made to the entity that is the legal owner on the date of discharge. Payments will not be prorated between the buyer and seller.

(1) The owner on the date of discharge is entitled to submit a bill for all inpatient hospital services furnished to a beneficiary regardless of when the beneficiary's coverage began

or ended during a stay, or of how long the stay lasted.

(2) Each bill submitted must include all information necessary for the intermediary to compute the payment amount, whether or not some of that information is attributable to a period during which a different party legally owned the hospital.

(b) Payment for capital-related costs and bad debts, as described in §§ 412.113(a) and 412.115(a), respectively, will be made to each owner or operator of the hospital (buyer and seller) in accordance with the principles of reasonable cost reimbursement.

Subparts I—J—[Reserved]

Subpart K—Prospective Payment System for Hospitals Located in Puerto Rico

SOURCE: 52 FR 33058, Sept. 1, 1987, unless otherwise noted.

§ 412.200 General provisions.

Beginning with discharges occurring on or after October 1, 1987, hospitals located in Puerto Rico are subject to the rules governing the prospective payment system. Except as provided in this subpart, the provisions of Subparts A, B, C, F, G, and H of this part apply to hospitals located in Puerto Rico, Except for § 412.60, which deals with DRG classification and weighting factors, the provisions of Subpart D and E, which describe the methodology used to determine prospective payment rates for hospitals, do not apply to hospitals located in Puerto Rico. Instead, the methodology for determining prospective payment rates for these hospitals is set forth in §§ 412.204 through 412.212.

§ 412.204 Payments to hospitals located in Puerto Rico.

Payments to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(a) 75 percent of the Puerto Rico prospective payment rate, as determined under § 412.208 or § 412.210; and

(b) 25 percent of a national prospective payment rate, as determined under § 412.212.

§ 412.208 Puerto Rico rates for Federal fiscal year 1988.

(a) *General rule.* HCFA determines the Puerto Rico adjusted DRG prospective payment rate for each inpatient hospital discharge occurring in Federal fiscal year 1988 for a prospective payment hospital. These rates are determined as described in paragraphs (b) through (i) of this section.

(b) *Determining target amounts.* For each hospital subject to the prospective payment system. HCFA determines the Medicare target amount, as described in § 413.40(c) of this chapter, for the hospital's cost reporting period beginning in fiscal year 1987. Revisions in the target amounts made subsequent to establishment of the standardized amounts under paragraph (d) of this section do not affect the standardized amounts.

(c) *Updating the target amounts for fiscal year 1988.* HCFA updates each target amount determined under paragraph (b) of this section for fiscal year 1988 by prorating the applicable percentage increase (as defined in § 412.63(f) of this chapter) for fiscal year 1988 to the midpoint of fiscal year 1988 (April 1, 1988).

(d) *Standardizing amounts.* HCFA standardizes the amount updated under paragraph (c) of this section for each hospital by—

(1) Adjusting for variations in case mix among hospitals;

(2) Excluding an estimate of indirect medical education costs;

(3) Adjusting for area variations in hospital wage levels; and

(4) Excluding an estimate of the payments for hospitals that serve a disproportionate share of low-income patients.

(e) *Computing urban and rural averages.* HCFA computes separate discharge-weighted averages of the standardized amounts determined under paragraph (d) of this section for urban and rural hospitals in Puerto Rico.

(f) *Geographic classification.* (1) For purposes of this paragraph (e) of this section, the following definitions apply:

(i) The term "urban area" means a Metropolitan Statistical Area (MSA), as defined by the Executive Office of Management and Budget.

(ii) The term "large urban area" means an MSA with a population of more than 1,000,000.

(iii) The term "rural area" means any area outside an urban area.

(2) A hospital classified as rural is deemed to be urban and receives the urban Puerto Rico payment amount if the county in which it is located meets the following criteria:

(i) At least 95 percent of the perimeter of the rural county is contiguous with urban counties.

(ii) The county was reclassified from an urban area to a rural area after April 20, 1983, as described in § 412.62(f)(1)(iv).

(iii) At least 15 percent of employed workers in the county commute to the central county of one of the adjacent MSAs.

(g) *Reducing for value of outlier payments.* HCFA reduces each of the average standardized amounts determined under paragraphs (c) through (e) of this section by a proportion equal to the proportion (estimated by HCFA) of the total amount of payments based on DRG prospective payment rates that are additional payments to hospitals located in Puerto Rico for outlier cases under Subpart F of this part.

(h) *Computing Puerto Rico rates for urban and rural hospitals.* For each discharge classified within a DRG, HCFA establishes a Puerto Rico prospective payment rate, as follows:

(1) For hospitals located in an urban area, the rate equals the product of—

(i) The average standardized amount (computed under paragraphs (c) through (g) of this section) for hospitals located in an urban area; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in a rural area, the rate equals the product of—

(i) The average standardized amount (computed under paragraphs (c) through (g) of this section) for hospitals located in a rural area; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(i) *Adjusting for different area wage levels.* HCFA adjusts the proportion (as estimated by HCFA from time to time) of Puerto Rico rates computed under paragraph (h) of this section that are attributable to wages and labor-related costs, for area differences in hospital wage levels, by a factor (established by HCFA) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (f) of this section) of the hospital compared to the national average hospital wage level.

[52 FR 33058, Sept. 1, 1987; 52 FR 35350, Sept. 18, 1987, as amended at 53 FR 38533, Sept. 30, 1988]

§ 412.210 Puerto Rico rates for fiscal years after Federal fiscal year 1988.

(a) *General rule.* (1) HCFA determines the Puerto Rico adjusted prospective payment rate for each inpatient hospital discharge occurring in a Federal fiscal year after fiscal year 1988 that involves inpatient hospital services of a hospital in Puerto Rico subject to the prospective payment system for which payment may be made under Medicare Part A.

(2) The rate is determined for hospitals located in large urban, other urban, or rural areas within Puerto Rico, as described in paragraphs (b) through (e) of this section.

(b) *Geographic classifications.* (1) For purposes of this section, the definitions set forth in § 412.208(f)(1) apply.

(2) For discharges occurring on or after October 1, 1988, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greatest number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under

the standards, from) the central county or central counties of all adjacent MSAs.

These EOMB standards are set forth in the notice of final standards for classification of MSAs published in the FEDERAL REGISTER on January 3, 1980 (45 FR 956), and available from HCFA, East High Rise Building, Room 132, 6325 Security Boulevard, Baltimore, Maryland 21207.

(3) For discharges occurring on or after October 1, 1988, for hospitals that consist of two or more separately located inpatient hospital facilities, the national adjusted prospective payment rate is based on the geographic location of the hospital at which the discharge occurs.

(c) *Updating previous standardized amounts.* HCFA computes separate average standardized amounts for hospitals in large urban, other urban, and rural areas within Puerto Rico equal to the respective average standardized amount computed for fiscal year 1988 under § 412.208(e)—

(1) Increased by the applicable percentage changes determined under § 412.63 (g) and (h); and

(2) Reduced by a proportion equal to the proportion (estimated by HCFA) of the total amount of prospective payments that are additional payment amounts to hospitals located in Puerto Rico attributable to outlier cases under Subpart F of this part.

(d) *Computing Puerto Rico rates for large urban, other urban, and rural hospitals.* For each discharge classified within a DRG, HCFA establishes for the fiscal year a Puerto Rico prospective payment rate as follows:

(1) For hospitals located in a large urban or other urban area in Puerto Rico, the rate equals the product of—

(i) The average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a large urban or other urban area; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in a rural area in Puerto Rico, the rate equals the product of—

(i) The average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a rural area; and

(ii) The weighting factor (determined under § 412.60(b)) for that DRG.

(e) *Adjusting for different area wage levels.* HCFA adjusts the proportion (as estimated by HCFA from time to time) of Puerto Rico rates computed under paragraph (d) of this section that is attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by HCFA) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the national average hospital wage level.

[52 FR 33058, Sept. 1, 1987, as amended at 53 FR 38533, Sept. 30, 1988]

§ 412.212 National rate.

(a) *General rule.* For purposes of payment to hospitals located in Puerto Rico, the national prospective payment rate is determined as described in paragraphs (b) through (d) of this section.

(b) *Computing a national average standardized amount.* HCFA computes a discharge-weighted average of the—

(1) National urban adjusted standardized amount determined under § 412.63(j)(1)(i); and

(2) National rural adjusted average standardized amount determined under § 412.63(j)(2)(i).

(c) *Computing a national rate.* For each discharge classified within a DRG, the national rate equals the product of—

(1) The national average standardized amount computed under paragraph (b) of this section; and

(2) The weighting factor (determined under § 412.60(b)) for that DRG.

(d) *Adjusting for different area wage levels.* HCFA adjusts the proportion (as estimated by HCFA from time to time) of the national rate computed under paragraph (c) of this section that is attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by HCFA) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

[52 FR 33058, Sept. 1, 1987, as amended at 53 FR 38533, Sept. 30, 1988]

§ 412.220 Special treatment of certain hospitals located in Puerto Rico.

Subpart G of this part sets forth rules for special treament of certain facilities under the prospective payment system. The following sections in Subpart G of this part do not apply to hospitals located in Puerto Rico:

(a) Section 412.92, sole community hospitals.

(b) Section 412.96, referral centers.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES

Subpart A—Introduction and General Rules

Sec.

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413.170 Payments for covered outpatient maintenance dialysis treatments.
413.174 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.
413.178 Reimbursement of independent organ procurement organizations and histocompatibility laboratories.

AUTHORITY: Secs. 1102, 1122, 1814(b), 1815, 1833(a), 1861(v), 1871, 1881, and 1886 of the Social Security Act as amended (42 U.S.C. 1302, 1320a-1, 1395f(b), 1395g, 1395l(a), 1395x(v), 1395hh, 1395rr, and 1395ww).

SOURCE: 51 FR 34793, Sept. 30, 1986, unless otherwise noted.

Subpart A—Introduction and General Rules

§ 413.1 Introduction.

(a) *Scope*—(1) *General summary.* This part sets forth regulations governing Medicare payment for services furnished to beneficiaries by—

(i) Hospitals;

(ii) Skilled nursing facilities (SNFs);

(iii) Home health agencies (HHAs);

(iv) Comprehensive outpatient rehabilitation facilities (CORFs);

(v) End-stage renal disease (ESRD) facilities;

(vi) Providers of outpatient physical therapy and speech pathology services (OPTs); and

(vii) Organ procurement agencies (OPAs) and histocompatibility laboratories.

(2) *Applicability.* The principles of payment and the related policies described in this part apply to HCFA, to the fiscal intermediaries acting as payors of claims on HCFA's behalf, to the Provider Reimbursement Review Board, and to the hospitals, SNFs, HHAs, CORFs, ESRD facilities, OPTs, OPAs, and histocompatibility laboratories receiving payment under this part.

(b) *Reasonable cost reimbursement.* Except as provided under paragraphs (c) through (e) of this section, Medicare is generally required, under section 1814(b) of the Act (for services covered under Part A) and under section 1833(a)(2) of the Act (for services covered under Part B) to pay for services furnished by providers on the basis of reasonable costs as defined in section 1861(v) of the Act, or the provider's customary charges for those services, if lower. Regulations implementing section 1861(v) are found generally in this part beginning at § 413.5.

(c) *Outpatient maintenance dialysis and related services.* Section 1881 of the Act authorizes special rules for the coverage of and payment for services furnished to ESRD patients. Sections 413.170 and 413.174 implement various provisions of section 1881. In particular, § 413.170 establishes a prospective payment method for outpatient maintenance dialysis services that applies both to hospital-based and independent ESRD facilities, and under which Medicare pays for both home and in-facility dialysis services furnished on or after August 1, 1983.

(d) *Payment for inpatient hospital services.* (1) For cost reporting periods beginning before October 1, 1983, the amount paid for inpatient hospital services is determined on a reasonable cost basis.

(2) For cost reporting periods beginning on or after October 1, 1983, payment to short-term general hospitals located in the 50 States and the District of Columbia for the operating costs of inpatient hospital services is determined prospectively on a per discharge basis under Part 412 of this chapter except as follows:

(i) Payment for capital-related, medical education, and kidney acquisition costs, and the costs of certain anesthesia services, is described in § 412.113 of this chapter.

(ii) Payment to children's, psychiatric, rehabilitation and long-term hospitals (as well as separate psychiatric and rehabilitation units (distinct parts) of short-term general hospitals), which are excluded from the prospective payment system under Subpart B of Part 412 of this chapter, and to hospitals outside the 50 States and the District of Columbia is on a reasonable cost basis, subject to the provisions of § 413.40.

(iii) Payment to hospitals subject to a State reimbursement control system is described in paragraph (e) of this section.

(e) *State reimbursement control systems.* Beginning October 1, 1983, Medicare reimbursement for inpatient hospital services may be made in accordance with a State reimbursement control system rather than under the Medicare reimbursement principles set forth in this part, if the State system is approved by HCFA. Regulations implementing this alternative reimbursement authority are set forth in Subpart C of Part 403 of this chapter.

§ 413.5 Cost reimbursement: General.

(a) In formulating methods for making fair and equitable reimbursement for services rendered beneficiaries of the program, payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. All necessary and proper expenses of an institution in the production of services, including normal standby costs, are recognized. Furthermore, the share of the total institutional cost that is borne by the program is related to the care furnished beneficiaries so that no part of their cost would need to be borne by other patients. Conversely, costs attributable to other patients of the institution are not to be borne by the program. Thus, the application of this approach, with appropriate accounting support, will result in meeting actual costs of services to beneficiaries as such costs vary from institution to institution. However, payments to providers of services for services furnished Medicare beneficiaries are subject to the provisions of §§ 413.13 and 413.30.

(b) Putting these several points together, certain tests have been evolved for the principles of reimbursement and certain goals have been established that they should be designed to accomplish. In general terms, these are the tests or objectives:

(1) That the methods of reimbursement should result in current payment so that institutions will not be disadvantaged, as they sometimes are under other arrangements, by having to put up money for the purchase of goods and services well before they receive reimbursement.

(2) That, in addition to current payment, there should be retroactive adjustment so that increases in costs are taken fully into account as they actually occurred, not just prospectively.

(3) That there be a division of the allowable costs between the beneficiaries of this program and the other patients of the provider that takes account of the actual use of services by the beneficiaries of this program and that is fair to each provider individually.

(4) That there be sufficient flexibility in the methods of reimbursement to be used, particularly at the beginning of the program, to take account of the great differences in the present state of development of recordkeeping.

(5) That the principles should result in the equitable treatment of both nonprofit organizations and profit-making organizations.

(6) That there should be a recognition of the need of hospitals and other providers to keep pace with growing needs and to make improvements.

(c) As formulated herein, the principles give recognition to such factors as depreciation, interest, bad debts, educational costs, compensation of owners, and an allowance for a reasonable return on equity capital of proprietary facilities. However, costs such as depreciation, interest on borrowed funds, a return on equity capital (in the case of certain proprietary providers), and other costs related to certain capital expenditures are subject to the provisions of § 413.161, "Nonallowable costs related to certain capital expenditures." With respect to allowable costs some items of inclusion and exclusion are:

(1) An appropriate part of the net cost of approved educational activities will be included.

(2) Costs incurred for research purposes, over and above usual patient care, will not be included.

(3) Grants, gifts, and income from endowments will not be deducted from operating costs unless they are designated by the donor for the payment of specific operating costs.

(4) The value of services provided by nonpaid workers, as members of an organization (including services of members of religious orders) having an agreement with the provider to furnish such services, is includable in the amount that would be paid others for similar work.

(5) Discounts and allowances received on the purchase of goods or services are reductions of the cost to which they relate.

(6) Bad debts growing out of the failure of a beneficiary to pay the deductible, or the coinsurance, will be reimbursed (after bona fide efforts at collection).

(7) Charity and courtesy allowances are not includable, although "fringe benefit" allowances for employees under a formal plan will be includable as part of their compensation.

(8) A reasonable allowance of compensation for the services of owners in profitmaking organizations will be allowed providing their services are actually performed in a necessary function.

(9) Reasonable cost of physicians' direct medical and surgical services (including supervision of interns and residents in the care of individual patients) furnished in a teaching hospital may be reimbursed as a provider cost (as described in § 405.465 of this chapter) where elected as provided for in § 405.521 of this chapter.

(d) In developing these principles of reimbursement for the Medicare program, all of the considerations inherent in allowances for depreciation were studied. The principles, as presented, provide options to meet varied situations. Depreciation will essentially be on an historical cost basis but since many institutions do not have adequate records of old assets, the principles provide an optional allowance in lieu of such depreciation for assets acquired before 1966. For assets acquired after 1965, the historical cost basis must be used. All assets actually in use for production of services for Medicare beneficiaries will be recognized even though they may have been fully or partially depreciated for other purposes. Assets financed with public funds may be depreciated. Although funding of depreciation is not required, there is an incentive for it since income from funded depreciation is not considered as an offset which must be taken to reduce the interest expense that is allowable as a program cost.

(e) A return on the equity capital of proprietary facilities, as described in § 413.157, is an allowance in addition to the reasonable cost of covered services furnished to beneficiaries.

(f) Renal dialysis items and services furnished under the ESRD provision are reimbursed and reported under §§ 413.170 and 413.174 respectively. For special rules concerning health maintenance organizations (HMOs), and providers of services and other health care facilities that are owned or operated by an HMO, or related to an HMO by common ownership or control, see §§ 417.242(b)(14) and 417.250(c) of this chapter.

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987]

§ 413.9 Cost related to patient care.

(a) *Principle.* All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, subject to principles relating to specific items of revenue and cost. However, for cost reporting periods beginning after December 31, 1973, payments to providers of services are based on the lesser of the reasonable cost of services covered under Medicare and furnished to program beneficiaries or the customary charges to the general public for such services, as provided for in § 413.13.

(b) *Definitions*—(1) *Reasonable cost.* Reasonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included. The regulations in this part take into account both direct and indirect costs of providers of services. The objective is that under the methods of determining costs, the costs with respect to individuals covered by the program will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by the program. These regulations also provide for the making of suitable retroactive adjustments after the provider has submitted fiscal and statistical reports. The retroactive adjustment will represent the difference between the amount received by the provider during the year for covered services from both Medicare and the beneficiaries and the amount determined in accordance with an accepted method of cost apportionment to be the actual cost of services furnished to beneficiaries during the year.

(2) *Necessary and proper costs.* Necessary and proper costs are costs that are appropriate and helpful in developing and maintaining the operation

of patient care facilities and activities. They are usually costs that are common and accepted occurrences in the field of the provider's activity.

(c) *Application.* (1) It is the intent of Medicare that payments to providers of services should be fair to the providers, to the contributors to the Medicare trust funds, and to other patients.

(2) The costs of providers' services vary from one provider to another and the variations generally reflect differences in scope of services and intensity of care. The provision in Medicare for payment of reasonable cost of services is intended to meet the actual costs, however widely they may vary from one institution to another. This is subject to a limitation if a particular institution's costs are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(3) The determination of reasonable cost of services must be based on cost related to the care of Medicare beneficiaries. Reasonable cost includes all necessary and proper expenses incurred in furnishing services, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. However, if the provider's operating costs include amounts not related to patient care, specifically not reimbursable under the program, or flowing from the provision of luxury items or services (that is, those items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services), such amounts will not be allowable. The reasonable cost basis of reimbursement contemplates that the providers of services would be reimbursed the actual costs of providing quality care however widely the actual costs may vary from provider to provider and from time to time for the same provider.

[51 FR 34795, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986]

§ 413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.

(a) *Definitions.* As used in this section—

"*Fair compensation*" means, for the purpose of providers that meet the nominal charge provisions in paragraph (f) of this section, the reasonable cost of covered services furnished to beneficiaries.

"*New provider*" means a provider that has operated as the type of facility for which it has been approved for participation in the Medicare program (for example, as a SNF or an HHA) under present and previous ownership for less than three full years.

"*Provider with a significant portion of low-income patients*" means a nonpublic provider whose charges are 60 percent or less of the reasonable cost represented by the charges, and that demonstrates, as required under paragraph (c)(1)(iii) of this section, that its charges are less than costs because its customary practice is to charge patients based on their ability to pay.

"*Public provider*" means a provider operated by a Federal, State, county, city, or other local government agency or instrumentality.

(b) *Application of the principle of lesser of costs or charges*—(1) *General rule.* Except as provided in paragraph (c) of this section, effective with cost reporting periods beginning on or after January 1, 1974, hospitals, SNFs, HHAs, and OPTs are paid the lesser of the reasonable cost (as described in paragaraph (d) of this section) of covered services furnished to beneficiaries or the customary charges (as defined in paragraph (e) of this section) made by the provider for the same services. The carryover of unreimbursed reasonable costs from previous cost reporting periods is recognized, in accordance with the provisions of paragraph (h) of this section.

(2) *Example.* A provider's reasonable cost for covered services furnished to Medicare beneficiaries during a cost reporting period is $125,000. The customary charges to those beneficiaries for these services is $110,000. The provider is to be reimbursed $110,000 less

deductible and coinsurance amounts that the beneficiaries are charged.

(c) *Providers and services not subject to the principle*—(1) *Providers*—(i) *CORFs.* Payment to CORFs is based on the reasonable cost of the services.

(ii) *Public providers.* Public providers furnishing services free of charge or at a nominal charge (as specified in paragraph (f) of this section) are paid fair compensation for services furnished to beneficiaries.

(iii) *Providers furnishing services to a significant portion of low-income patients.* Effective with cost reporting periods beginning on or after October 1, 1984, a provider furnishing services at a nominal charge (as specified in paragraph (f) of this section) is paid fair compensation, upon request, for services furnished to beneficiaries if the provider can demonstrate to its intermediary that a significant portion of its patients are low income and that its charges are less than costs because its customary practice is to charge patients based on their ability to pay.

(2) *Services*—(i) *Part A inpatient hospital services.* The lesser of costs or charges principle does not apply to Part A inpatient hospital services subject to—

(A) The rate-of-increase limits under § 413.40, effective with cost reporting periods beginning on or after October 1, 1982; or

(B) The prospective payment system under Part 412 of this chapter, effective with cost reporting periods beginning on or after October 1, 1983.

(ii) *Special rule for facility services related to ambulatory surgical procedures performed in outpatient hospital departments.* Effective for hospitals with cost reporting periods beginning on or after October 1, 1987, reasonable costs and customary charges for those services relating to ambulatory surgical procedures that are subject to the payment methodology described in § 413.118 are aggregated and treated separately from all other hospital costs and charges incurred during the cost reporting period.

(iii) *Durable medical equipment furnished by HHAs*—(A) *General.* Except as provided in paragraph (c)(2)(iii)(B) of this section, for durable medical equipment furnished by an HHA as a home health service on or after July 18, 1984, the HHA is paid the lesser of the reasonable cost of the equipment or the customary charges (less a 20 percent coinsurance as provided in section 1866(a)(2)(A)(ii) of the Act), not to exceed 80 percent of the reasonable cost of the equipment. The lesser of cost or charges determination for durable medical equipment is made separately from all other items or services furnished in an HHA regardless of whether the equipment is furnished under Part A or Part B.

(B) *HHAs meeting the nominal charge provisions.* A public HHA, or an HHA that demonstrates that a significant portion of its patients are low-income patients under the nominal charge provisions, as provided in paragraph (f)(2) of this section, are paid 80 percent of fair compensation for durable medical equipment furnished as a home health service on or after July 18, 1984.

(d) *Exclusions from reasonable cost.* For purposes of comparison with customary charges under this section, reasonable cost does not include—

(1) Payments made to a provider as reimbursement for bad debts arising from noncollection of Medicare deductible and coinsurance amounts (§ 413.80);

(2) Amounts that represent the recovery of excess depreciation resulting from termination in the Medicare program or a decrease in Medicare utilization (§ 413.134(d)(3)) applicable to prior cost reporting periods;

(3) Amounts that result from a disposition of depreciable assets (§ 413.134(f)) applicable to prior cost reporting periods; and

(4) Payments to funds for the donated services of teaching physicians (§ 413.85).

(e) *Customary charges*—(1) *General.* As used in this paragraph (e), customary charges means the charges for services, as defined in § 413.53(b), furnished to beneficiaries. These charges must be recorded on all bills submitted for program reimbursement.

(2) *Special situations in which customary charges are reduced.* Customary charges are reduced in proportion to the ratio of the aggregate amount actually collected from charge-paying

non-Medicare patients to the amount that would have been realized had customary charges been paid and the provider—

(i) Did not actually impose charges in the case of most patients liable for payment for its services on a charge basis; or

(ii) Failed to make a reasonable effort to collect those charges.

(f) *Nominal charges*—(1) *Cost reporting periods beginning before October 1, 1984.* Except for durable medical equipment furnished by HHAs as provided in paragraph (c)(2)(iii) of this section, if a public provider's total charges, for cost reporting periods beginning before October 1, 1984, are less than one-half of the reasonable cost of services or items represented by these charges, then the provider is reimbursed fair compensation.

(2) *Cost reporting periods beginning on or after October 1, 1984.* For cost reporting periods beginning on or after October 1, 1984, the following provisions apply in determining nominal charges:

(i) *Reimbursement of fair compensation.* Except for the limitations on reimbursement for durable medical equipment furnished by HHAs as provided in paragraph (c)(2)(iii) of this section, public providers, and providers with a significant portion of low-income patients that request payment under this paragraph are reimbursed fair compensation if total charges are 60 percent or less of the reasonable cost of services or items represented by these charges.

(ii) *Separate determination of nominal charges.* Except as provided in paragraph (f)(2)(iii) of this section, the determination of nominal charges, which is based on charges actually billed to charge-paying, non-Medicare patients, is made separately with respect to inpatient and outpatient services (other than clinical diagnostic laboratory tests that are paid under section 1833(h) of the Act).

(iii) *Determination of nominal charges in special situations.* (A) For providers that have a sliding scale or discounted schedule of charges based on patients' ability to pay, the determination of nominal charges is based on charges billed to all charge-paying patients. This determination is made using the ratio of sliding scale or discounted charges to the provider's full customary charges. For determining nominal charges, the ratio is applied to the provider's Medicare charges to equate those charges to customary charges.

(B) For HHAs, the determination of nominal charges for all items and services other than durable medical equipment is made on an aggregate basis. The nominal charge determination for durable medical equipment is made separately from other items or services furnished by HHAs.

(g) *The aggregation method*—(1) *Cost reporting periods beginning before October 1, 1984—Application.* In comparing costs and charges under the lesser of costs or charges principle for cost reporting periods beginning before October 1, 1984, the reasonable cost for items and services and the customary charges for those same items and services are to be aggregated (that is, totalled and compared) without regard to whether the services are reimbursable under Part A or Part B of Medicare. This aggregation method is to be applied after the provider's charges and costs have been adjusted to exclude the amounts described in paragraph (d) of this section and to exclude—

(i) Any amounts attributable to physican services not reimbursable to the provider on a reasonable cost basis as described in §§ 405.480 through 405.482 of this chapter; and

(ii) All costs and charges for noncovered provider services.

(2) *Cost reporting periods beginning on or after October 1, 1984.* Effective with cost reporting periods beginning on or after October 1, 1984, the aggregation method used for computing the lesser of costs or charges, as set forth in paragraph (g)(1) of this section, may not be used. For covered items and services furnished during these periods, total reasonable cost of covered items and services is compared with total customary charges for those items and services, separately for Part A and for Part B.

(h) *Accumulation of unreimbursed costs and carryover to subsequent periods*—(1) *General rule.* A provider whose charges are lower than its reasonable cost for those services in any cost reporting period beginning on or after January 1, 1974 but before April 28, 1988, may carry forward costs that are unreimbursed under paragraph (b) of this section for the two succeeding cost reporting periods. However, no recovery may be made in any period in which costs are unreimbursed because a provider's costs exceed the limitations on reimbursable costs (§ 413.30) or the ceiling on the rate of hospital cost increases (§ 413.40).

(2) *Reimbursement as a result of carryover.* The provider is reimbursed for the costs that are carried forward to a succeeding cost reporting period—

(i) If total charges for services provided in that subsequent period exceed the total reasonable cost of the services; and

(ii) To the extent that accumulation of the costs being carried forward and the costs for the services provided in that subsequent period do not exceed the customary charges for those services.

(3) *Two succeeding periods less than 24 months.* If the two succeeding cost reporting periods are less than 24 full calendar months, the provider may carry forward the unreimbursed costs for one additional cost reporting period.

(4) *Example.* In the cost reporting period ending September 30, 1982, a provider's reasonable costs were $100,000. The provider's customary charges for those services were $90,000. The provider is reimbursed $90,000 less any deductible and coinsurance amounts but is permitted to carry forward the unreimbursed reasonable costs of $10,000 for the next two succeeding cost reporting periods. If, in the cost reporting period ending September 30, 1983, customary charges to beneficiaries exceeded the reasonable costs for those services by $10,000 or more, and the provider had no costs unreimbursed under § 413.30 or § 413.40, the provider would recover the entire $10,000 previously not reimbursed. If, however, beneficiary charges for that cost reporting period exceeded costs by only $8,000, this amount ($8,000) would be added to the provider's reimbursable costs for this period. The balance of the unreimbursed amount ($2,000) would be carried forward to the next cost reporting period.

(5) *New providers*—(i) *General rule.* A new provider whose cost reporting period begins before April 28, 1988, may carry forward costs that are unreimbursed from previous periods, as described in paragraph (b) of this section, during a provider's base period. The base period includes any cost reporting period beginning on or after January 1, 1974, and ending on or before the last day of its third year of operation. The unreimbursed costs may be carried forward for the five succeeding cost reporting periods. However, no recovery may be made in any period in which costs are unreimbursed because a provider's costs exceed the limitations on reimbursable costs (§ 413.30) or the ceiling on the rate of hospital cost increases (§ 413.40).

(ii) *Reimbursement as a result of carryover.* The new provider is reimbursed for the costs that are carried forward to a succeeding cost reporting period—

(A) If total charges for the services provided in that subsequent period exceed the total reasonable cost of the services; and

(B) To the extent that accumulation of the costs being carried forward and the costs for the services provided in that subsequent period do not exceed the customary charges for those services.

(iii) *Five succeeding periods less than 60 months.* If the five succeeding cost reporting periods are less than 60 full calendar months, the provider may carry forward the unreimbursed costs for one additional cost reporting period.

(iv) *Example.* A provider begins its operations on March 5, 1972. However, it begins to participate in the Medicare program as of January 1, 1973, and reports on a calendar year basis. Because the provider would be subject to the lesser of cost or charges principle for its cost reporting period beginning with January 1, 1974, it would be permitted to accumulate any unreimbursed costs (excess of costs over its charges) incurred during this reporting period. Therefore, because this cost reporting period ends before the end of the third year of operation, its carryover period would be the succeeding five cost reporting periods ending with December 31, 1979. If this provider had begun its operation on July 1, 1973, and become a participating provider as of the same date (with a fiscal year ending June 30), it would have been able to accumulate any unreimbursed costs for the two cost reporting periods ending June 30, 1975, and June 30, 1976. Its carryover period would then be the five cost reporting periods ending no later than June 30, 1981, in the case of costs unreimbursed in either of the reporting periods ending June 30, 1975, or June 30, 1976.

[53 FR 10085, Mar. 29, 1988; 53 FR 12641, Apr. 15, 1988]

§ 413.17 Cost to related organizations.

(a) *Principle.* Except as provided in paragraph (d) of this section, costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization. However, such cost must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.

(b) *Definitions*—(1) *Related to the provider.* Related to the provider means that the provider to a significant extent is associated or affiliated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.

(2) *Common ownership.* Common ownership exists if an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.

(3) *Control.* Control exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(c) *Application.* (1) Individuals and organizations associate with others for various reasons and by various means. Some deem it appropriate to do so to assure a steady flow of supplies or services, to reduce competition, to gain a tax advantage, to extend influence, and for other reasons. These goals may be accomplished by means of ownership or control, by financial assistance, by management assistance, and other ways.

(2) If the provider obtains items of services, facilities, or supplies from an organization, even though it is a separate legal entity, and the organization is owned or controlled by the owner(s) of the provider, in effect the items are obtained from itself. An example would be a corporation building a hospital or a nursing home and then leasing it to another corporation controlled by the owner. Therefore, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the price in the open market for comparable services, facilities, or supplies is lower than the cost to the supplier, the allowable cost to the provider may not exceed the market price.

(d) *Exception.* (1) An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the fiscal intermediary (or, if the provider has not nominated a fiscal intermediary, HCFA), that—

(i) The supplying organization is a bona fide separate organization;

(ii) A substantial part of its business activity of the type carried on with the provider is transacted with others than the provider and organizations related to the supplier by common ownership or control and there is an open, competitive market for the type of services, facilities, or supplies furnished by the organization;

(iii) The services, facilities, or supplies are those that commonly are obtained by institutions such as the provider from other organizations and are not a basic element of patient care ordinarily furnished directly to patients by such institutions; and

(iv) The charge to the provider is in line with the charge for such services, facilities, or supplies in the open market and no more than the charge made under comparable circumstances to others by the organization for such services, facilities, or supplies.

(2) In such cases, the charge by the supplier to the provider for such services, facilities, or supplies is allowable as cost.

Subpart B—Accounting Records and Reports

§ 413.20 Financial data and reports.

(a) *General.* The principles of cost reimbursement require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program. Standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields are followed. Changes in these practices and systems will not be required in order to determine costs payable under the principles of reimbursement. Essentially the methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services to beneficiaries.

(b) *Frequency of cost reports.* Cost reports are required from providers on an annual basis with reporting periods based on the provider's accounting year. In the interpretation and application of the principles of reimbursement, the fiscal intermediaries will be an important source of consultative assistance to providers and will be available to deal with questions and problems on a day-to-day basis.

(c) *Recordkeeping requirements for new providers.* A newly participating provider of services (as defined in § 400.202 of this chapter) must make available to its selected intermediary for examination its fiscal and other records for the purpose of determining such provider's ongoing recordkeeping capability and inform the intermediary of the date its initial Medicare cost reporting period ends. This examination is intended to assure that—

(1) The provider has an adequate ongoing system for furnishing the records needed to provide accurate cost data and other information capable of verification by qualified auditors and adequate for cost reporting purposes under section 1815 of the Act; and

(2) No financial arrangements exist that will thwart the commitment of the Medicare program to reimburse providers the reasonable cost of services furnished beneficiaries. The data and information to be examined include cost, revenue, statistical, and other information pertinent to reimbursement including, but not limited to, that described in paragraph (d) of this section and in § 413.24.

(d) *Continuing provider recordkeeping requirements.* (1) The provider must furnish such information to the intermediary as may be necessary to—

(i) Assure proper payment by the program, including the extent to which there is any common ownership or control (as described in § 413.17(b)(2) and (3)) between providers or other organizations, and as may be needed to identify the parties responsible for submitting program cost reports;

(ii) Receive program payments; and

(iii) Satisfy program overpayment determinations.

(2) The provider must permit the intermediary to examine such records and documents as are necessary to ascertain information pertinent to the determination of the proper amount of program payments due. These records include, but are not limited to, matters pertaining to—

(i) Provider ownership, organization, and operation;

(ii) Fiscal, medical, and other recordkeeping systems;

(iii) Federal income tax status;

(iv) Asset acquisition, lease, sale, or other action;

(v) Franchise or management arrangements;

(vi) Patient service charge schedules;

(vii) Costs of operation;

(viii) Amounts of income received by source and purpose; and

(ix) Flow of funds and working capital.

(3) The provider, upon request, must furnish the intermediary copies of patient service charge schedules and changes thereto as they are put into effect. The intermediary will evaluate such charge schedules to determine

the extent to which they may be used for determining program payment.

(e) *Suspension of program payments to a provider.* If an intermediary determines that a provider does not maintain or no longer maintains adequate records for the determination of reasonable cost under the Medicare program, payments to such provider will be suspended until the intermediary is assured that adequate records are maintained. Before suspending payments to a provider, the intermediary will, in accordance with the provisions in § 405.371(a) of this chapter, send written notice to such provider of its intent to suspend payments. The notice will explain the basis for the intermediary's determination with respect to the provider's records and will identify the provider's recordkeeping deficiencies. The provider must be given the opportunity, in accordance with § 405.371(a) of this chapter, to submit a statement (including any pertinent evidence) as to why the suspension must not be put into effect.

§ 413.24 Adequate cost data and cost finding.

(a) *Principle.* Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting. However, if governmental institutions operate on a cash basis of accounting, cost data based on such basis of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

(b) *Definitions*—(1) *Cost finding.* Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished. It is the determination of these costs by the allocation of direct costs and proration of indirect costs.

(2) *Accrual basis of accounting.* Under the accrual basis of accounting, revenue is reported in the period when it is earned, regardless of when it is collected, and expenses are reported in the period in which they are incurred, regardless of when they are paid.

(c) *Adequacy of cost information.* Adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended. Adequate data capable of being audited is consistent with good business concepts and effective and efficient management of any organization, whether it is operated for profit or on a nonprofit basis. It is a reasonable expectation on the part of any agency paying for services on a cost-reimbursement basis. In order to provide the required cost data and not impair comparability, financial and statistical records should be maintained in a manner consistent from one period to another. However, a proper regard for consistency need not preclude a desirable change in accounting procedures if there is reason to effect such change.

(d) *Cost finding methods.* After the close of the accounting period, providers must use one of the following methods of cost finding to determine the actual costs of services furnished during that period. For cost reporting periods beginning after December 31, 1971, providers using the departmental method of cost apportionment must use the step-down method described in paragraph (d)(1) of this section or an "other method" described in paragraph (d)(2) of this section. For cost reporting periods beginning after December 31, 1971, providers using the combination method of cost apportionment must use the modified cost finding method described in paragraph (d)(3) of this section. Effective for cost reporting periods beginning on or after October 1, 1980, HHAs not based in hospitals or SNFs must use the step-down method described in paragraph (d)(1) of this section. (HHAs based in hospitals or SNFs must use the method applicable to the parent institution.) However, an HHA not based in a hospital or SNF that received less than $35,000 in Medicare reimbursement for the immediately preceding cost reporting period, and for whom this reimbursement represented less than 50 percent of the total operating cost of the agency, may use a simplified version of the step-down method, as specified in instructions for the cost report issued by HCFA.

(1) *Step-down Method.* This method recognizes that services furnished by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers as well as by the revenue-producing centers. All costs of nonrevenue-producing centers are allocated to all centers that they serve, regardless of whether or not these centers produce revenue. The cost of the nonrevenue-producing center serving the greatest number of other centers, while receiving benefits from the least number of centers, is apportioned first. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered "closed" and no further costs are apportioned to that center. This applies even though it may have received some service from a center whose cost is apportioned later. Generally, if two centers furnish services to an equal number of centers while receiving benefits from an equal number, that center which has the greatest amount of expense should be allocated first.

(2) *Other methods*—(i) *The double-apportionment method.* The double-apportionment method may be used by a provider upon approval of the intermediary. This method also recognizes that the nonrevenue-producing departments or centers furnish services to other nonrevenue-producing centers as well as to revenue-producing centers. A preliminary allocation of the costs of non-revenue-producing centers is made. These centers or departments are not "closed" after this preliminary allocation. Instead, they remain "open," accumulating a portion of the costs of all other centers from which services are received. Thus, after the first or preliminary allocation, some costs will remain in each center representing services received from other centers. The first or preliminary allocation is followed by a second or final apportionment of expenses involving the allocation of all costs remaining in the nonrevenue-producing functions directly to revenue-producing centers.

(ii) *More sophisticated methods.* A more sophisticated method designed to allocate costs more accurately may be used by the provider upon approval of the intermediary. However, having elected to use the double-apportionment method, the provider may not thereafter use the step-down method without approval of the intermediary. Written request for the approval must be made on a prospective basis and must be submitted before the end of the fourth month of the prospective reporting period. Likewise, once having elected to use a more sophisticated method, the provider may not thereafter use either the double-apportionment or step-down methods without similar request and approval.

(3) *Modified cost finding for providers using the Combination Method for reporting periods beginning after December 31, 1971.* This method differs from the step-down method in that services furnished by nonrevenue-producing departments or centers are allocated directly to revenue-producing departments or centers even though these services may be utilized by other nonrevenue-producing departments or centers. In the application of this method the cost of nonrevenue-producing centers having a common basis of allocation are combined and the total distributed to revenue-producing centers. All nonrevenue-producing centers having significant percentages of cost in relation to total costs will be allocated this way. The combined total costs of remaining nonrevenue-producing costs centers will be allocated to revenue-producing cost centers in the proportion that each bears to total costs, direct and indirect, already allocated. The bases which are to be used and the centers which are to be combined for allocation are not optional but are identified and incorporated in the cost report forms developed for this method. Providers using this method must use the program cost report forms devised for it. Alternative forms may not be used without prior approval by HCFA based upon a written request by the provider submitted through the intermediary.

(4) *Temporary method for initial period.* If the provider is unable to use either cost-finding method when it first participates in the program, it may apply to the intermediary for permission to use some other acceptable method that would accurately identify costs by department or center, and appropriately segregate inpatient and outpatient costs. Such other method may be used for cost reports covering periods ending before January 1, 1968.

(5) *Simplified optional reimbursement method for small rural hospitals with distinct parts for cost reporting periods beginning on or after July 20, 1982.* (i) A rural hospital with a Medicare-certified distinct part SNF may elect to be reimbursed for services furnished in its hospital general routine service area and distinct part SNF using the reimbursement method specified in § 413.53 for swing-bed hospitals, if it meets the following conditions:

(A) The institution is located in a rural area as defined in § 482.66 of this chapter.

(B) On the first day of the cost reporting period, the hospital and distinct part SNF have fewer than 50 beds in total (with the exception of beds for newborns and beds in intensive care type inpatient units).

(ii) In applying the optional reimbursement method, only those beds located in the hospital general routine service area and in the distinct part SNF certified by Medicare are combined into a single cost center for purposes of cost finding.

(iii) The reasonable cost of the routine extended care services is determined in accordance with § 413.114(c). The reasonable cost of the hospital general routine services is determined in accordance with § 413.53(a)(2).

(iv) The hospital must make its election to use the optional swing-bed reimbursement method in writing to the intermediary before the beginning of the hospital's cost reporting year. The hospital must make any request to revoke the election in writing before the beginning of the affected cost reporting period.

(v) The intermediary must approve requests to terminate use of the optional swing-bed reimbursement method. If a hospital terminates use of this optional method, no further elections may be made by the facility to use the optional method.

(e) *Accounting basis.* The cost data submitted must be based on the accrual basis of accounting which is recognized as the most accurate basis for determining costs. However, governmental institutions that operate on a cash basis of accounting may submit cost data on the cash basis subject to appropriate treatment of capital expenditures.

(f) *Cost reports.* For cost reporting purposes, the Medicare program requires each provider of services to submit periodic reports of its operations that generally cover a consecutive 12-month period of the provider's operations. Amended cost reports to revise cost report information that has been previously submitted by a provider may be permitted or required as determined by HCFA.

(1) *Cost reports—Terminated providers and changes of ownership.* A provider that voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change of ownership must file a cost report for that period under the program beginning with the first day not included in a previous cost reporting period and ending with the effective date of termination of its provider agreement or change of ownership.

(2) *Due dates for cost reports.* (i) Cost reports are due on or before the last day of the third month following the close of the period covered by the report.

(ii) A 30-day extension of the due date of a cost report may, for good cause, be granted by the intermediary, after first obtaining the approval of HCFA.

(iii) The cost report from a provider that voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change of ownership is due no later than 45 days following the effective date of the termination of the provider agreement or change of ownership.

(3) *Changes in cost reporting periods.* A provider may change its cost reporting period if a change in ownership is experienced or if the—

(i) Provider requests the change in writing from its intermediary;

(ii) Intermediary receives the request at least 120 days before the close of the new reporting period requested by the provider; and

(iii) Intermediary determines that good cause for the change exists. Good cause would not be found to exist if the effect is to change the initial date that a hospital would be affected by the rate of increase ceiling (see § 413.40), or be paid under the prospective payment system (see Part 412 of this chapter).

(g) *Exception from full cost reporting for lack of program utilization.* If a provider does not furnish any covered services to Medicare beneficiaries during a cost reporting period, it is not required to submit a full cost report. It must, however, submit an abbreviated cost report, as prescribed by HCFA.

(h) *Waiver of full cost reporting for low program utilization.* (1) If the provider has had low utilization of covered services by Medicare beneficiaries (as determined by the intermediary) and has received correspondingly low interim reimbursement payments for the cost reporting period, the intermediary may waive a full cost report if it decides that it can determine, without a full report, the reasonable cost of covered services provided during that period.

(2) If a full cost report is waived, the provider must submit within the same time period required for full cost reports:

(i) The cost reporting forms prescribed by HCFA for this situation; and

(ii) Any other financial and statistical data the intermediary requires.

Subpart C—Limits on Cost Reimbursement

§ 413.30 Limitations on reimbursable costs.

(a) *Introduction*—(1) *Scope.* This section implements section 1861(v)(1)(A) of the Act, by setting forth the general rules under which HCFA may establish limits on provider costs recognized as reasonable in determining Medicare program payments, and sections 1861(v)(7)(B) and 1886(a) of the Act, by setting forth the general rules under which HCFA may establish limits on the operating costs of inpatient hospital services that are recognized as reasonable in determining Medicare program payments. (For cost reporting periods beginning on or after October 1, 1983, the operating costs incurred in furnishing inpatient hospital services are not subject to the provisions of this section.) This section also sets forth rules governing exemptions, exceptions, and adjustments to limits established under this section that HCFA may make as appropriate in consideration of special needs or situations of particular providers.

(2) *General principle.* Reimbursable provider costs may not exceed the costs estimated by HCFA to be necessary for the efficient delivery of needed health services. HCFA may establish estimated cost limits for direct or indirect overall costs or for costs of specific items or services or groups of items or services. These limits will be imposed prospectively and may be calculated on a per admission, per discharge, per diem, per visit, or other basis.

(b) *Procedure for establishing limits.* (1) In establishing limits under this section, HCFA may classify providers by type of provider (for example, hospitals, SNFs, and HHAs) and by other factors HCFA finds appropriate and practical, including—

(i) Type of services furnished;

(ii) Geographical area where services are furnished, allowing for grouping of noncontiguous areas having similar demographic and economic characteristics;

(iii) Size of institution;

(iv) Nature and mix of services furnished; or

(v) Type and mix of patients treated.

(2) Estimates of the costs necessary for efficient delivery of health services may be based on cost reports or other data providing indicators of current costs. Current and past period data will be adjusted to arrive at estimated costs for the prospective periods to which limits are being applied.

(3) Prior to the beginning of a cost period to which revised limits will be applied, HCFA will publish a notice in the FEDERAL REGISTER, establishing

cost limits and explaining the basis on which they were calculated.

(4) In establishing limits under paragraph (b)(1) of this section, HCFA may find it inappropriate to apply particular limits to a class of providers due to the characteristics of the provider class, the data on which those limits are based, or the method by which the limits are determined. In such cases, HCFA may exclude that class of providers from the limits, explaining the basis of the exclusion in the notice setting forth the limits for the appropriate cost reporting periods.

(c) *Provider requests regarding applicability of cost limits.* A provider may request a reclassification, exception, or exemption from the cost limits imposed under this section. In addition, a hospital may request an adjustment to the cost limits imposed under this section. The provider's request must be made to its fiscal intermediary within 180 days of the date on the intermediary's notice of program reimbursement. The intermediary makes a recommendation on the provider's request to HCFA, which makes the decision. HCFA responds to the request within 180 days from the date HCFA receives the request from the intermediary. The intermediary notifies the provider of HCFA's decision. The time required for HCFA to review the request is considered good cause for the granting of an extension of the time limit to apply for a Board review, as specified in § 405.1841 of this chapter. HCFA's decision is subject to review under Subpart R of Part 405 of this chapter.

(d) *Reclassification.* A provider may obtain a reclassification if it can show that its classification is at variance with the criteria specified in promulgating the limits.

(e) *Exemptions.* Exemptions from the limits imposed under this section may be granted in the following circumstances:

(1) *Sole community hospital.* A sole community hospital is a hospital which, by reason of factors such as isolated location or absence of other hospitals, is the sole source of such care reasonably available to beneficiaries.

(2) *New provider.* The provider of inpatient services has operated as the type of provider (or the equivalent) for which it is certified for Medicare, under present and previous ownership, for less than three full years. An exemption granted under this paragraph expires at the end of the provider's first cost reporting period beginning at least two years after the provider accepts its first patient.

(3) *Risk-basis HMO.* The items or services are furnished to beneficiaries enrolled in an HMO by a provider that is either owned or operated by a risk-basis HMO or related to a risk-basis HMO by common ownership or control (see § 417.250(c)).

(4) *Rural hospital with less than 50 beds.* The hospital—

(i) Was in operation with less than 50 beds as of September 3, 1982;

(ii) Has less than 50 beds throughout the applicable cost reporting period; and

(iii) Is outside the boundaries of all Standard Metropolitan Statistical Areas as designated by the Executive Office of Management and Budget.

(f) *Exceptions.* Limits established under this section may be adjusted upward for a provider under the circumstances specified in paragraphs (f)(1) through (f)(8) of this section, and may be adjusted upward or downward under the circumstances specified in paragraph (f)(9) of this section. An ajdustment is made only to the extent the costs are reasonable, attributable to the circumstances specified, separately identified by the provider, and verified by the intermediary.

(1) *Atypical services.* The provider can show that the—

(i) Actual cost of items or services furnished by a provider exceeds the applicable limit because such items or services are atypical in nature and scope, compared to the items or services generally furnished by providers similarly classified; and

(ii) Atypical items or services are furnished because of the special needs of the patients treated and are necessary in the efficient delivery of needed health care.

(2) *Extraordinary circumstances.* The provider can show that it incurred higher costs due to extraordinary circumstances beyond its control. These circumstances include, but are not lim-

ited to, strikes, fire, earthquake, flood, or similar unusual occurrences with substantial cost effects.

(3) *Providers in areas with fluctuating populations.* (i) The provider is located in an area (for example, a resort area) that has a population that varies significantly during the year;

(ii) The appropriate health planning agency has determined that the area does not have a surplus of beds and similar services and has certified that the beds and services made available by the provider are necessary; and

(iii) The provider meets occupancy standards established by the Secretary.

(4) *Medical and paramedical education.* The provider can demonstrate that, if compared to other providers in its group, it incurs increased costs for items or services covered by limits under this section because of its operation of an approved education program specified in § 413.85.

(5) *More intensive routine care for cost reporting periods beginning before October 1, 1982.* The hospital—

(i) Is subject to per diem limits on inpatient general routine operating costs issued under paragraph (b)(3) of this section;

(ii) Furnishes a greater intensity of inpatient general routine operating care than other hospitals having a reasonably similar mix of patients; and

(iii) Shows that the more intensive care results in a shorter average length of stay and higher per unit costs than in comparable hospitals.

(6) *Essential community hospital services exception.* The Secretary finds that—

(i) The hospital exceeds its applicable limit by more than 15 percent;

(ii) Full application of the limits would render the hospital insolvent;

(iii) Such insolvency would deprive the community of essential services; and

(iv) The hospital has taken, or provided adequate assurances that it plans to take, all available efficiency and economy measures to bring its costs into line with those of comparable facilities. In this case, the Secretary may grant an exception to the limit for the amount by which the hospital exceeds 115 percent of its applicable limit for such period as he deems necessary (but not to exceed the period during which the hospital meets the enumerated conditions).

(7) [Reserved]

(8) *Unusual labor costs.* The provider has a percentage of labor costs that varies more than 10 percent from that included in the promulgation of the limits.

(9) *Changes in case mix for cost reporting periods beginning before October 1, 1983.* The hospital—

(i) Is subject to limits issued under paragraph (b)(3) of this section for cost reporting periods beginning before October 1, 1983, that are calculated by use of a case-mix index;

(ii) Has added or discontinued services in a year after the year represented in the discharge data used to establish the limits described in paragraph (f)(9)(i) of this section;

(iii) Has experienced a significant and abrupt change in case mix as a result of the addition or deletion of services; and

(iv) Submits discharge data, in the format required by HCFA, for Medicare discharges in the cost reporting period for which the exception is requested.

(g) *Operational review of providers receiving an exception.* Any provider that applies for an exception to the limits established under paragraph (f) of this section must agree to an operational review at the discretion of HCFA. The findings from any such review may be the basis for recommendations for improvements in the efficiency and economy of the provider's operations. If such recommendations are made, any future exceptions shall be contingent on the provider's implementation of these recommendations.

(h) *Adjustments.* For cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983, HCFA may adjust the amount of a hospital's inpatient operating costs to take into account factors that could result in a significant distortion in the operating costs of inpatient hospital services. Such factors could include a decrease in the inpatient services that a hospital provides that are customarily provided directly by similar hospitals, or the manipulation of discharges to increase reimbursement. A decrease in inpatient services could result from changes that include, but are not limited to, such actions as closing a special care unit or changing the arrangements under which such services may be furnished, such as leasing a department.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 53 FR 38533, Sept. 30, 1988]

§ 413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.

(a) *Principle.* A provider of services that customarily furnishes an individual items or services that are more expensive than the items or services determined to be necessary in the efficient delivery of needed health services described in § 413.30, may charge an individual entitled to benefits under Medicare for such more expensive items or services even though not requested by the individual. The charge, however, may not exceed the amount by which the cost of (or, if less, the customary charges for) such more expensive items or services furnished by such provider in the second cost reporting period immediately preceding the cost reporting period in which such charges are imposed exceeds the applicable limit imposed under the provisions of § 413.30. This charge may be made only if—

(1) The intermediary determines that the charges have been calculated properly in accordance with the provisions of this section;

(2) The services are not emergency services as defined in paragraph (d) of this section;

(3) The admitting physician has no direct or indirect financial interest in such provider;

(4) HCFA has provided notice to the public through notice in a newspaper of general circulation servicing the provider's locality and such other notice as the Secretary may require, of any charges the provider is authorized to impose on individuals entitled to benefits under Medicare on account of costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare; and

(5) The provider has, in the manner described in paragraph (e) of this section, identified such charges to such individual or person acting on his behalf as charges to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare.

(b) *Provider request to charge beneficiaries for costs in excess of limits.* (1) If a provider's actual costs (or, if less, the customary charges) in the second preceding cost period exceed the prospective limits established for such costs, the intermediary will, at the provider's request, validate in advance the charges that may be made to the beneficiaries for the excess.

(2) If a provider does not have a second preceding cost period and is a new provider as defined in § 413.30(e)(2), the provider, subject to validation by the intermediary, will estimate the current cost of the service to which a limit is being applied. Such amount will be adjusted to an amount equivalent to costs in the second preceding year by use of a factor to be developed based on estimates of cost increases during the preceding two years and published by SSA or HCFA. The amount thus derived will be used in lieu of the second preceding cost period amount in determining the charge to the beneficiary.

(3) To obtain consideration of such a request, the provider must submit to the intermediary a statement indicating the chagre for which it is seeking validation and providing the data and method used to determine the amount. Such statement should include the—

(i) Provider's name and number;

(ii) Identity of class and prospective cost limit for the class in which the provider has been included;

(iii) Amount of charge and cost period in which the charge is to be imposed;

(iv) Cost and customary charge for items and services furnished to beneficiaries; and

(v) Cost period ending date of the second reporting period immediately preceding the cost period in which the charge is to be imposed. The intermediary may request such additional information as it finds necessary with respect to the request.

(c) *Provider charges—(1) Establishing the charges.* If the actual cost incurred (or, if less, the customary charges) in the prior period determined under paragraph (a) of this section exceeds the limits applicable to the pertinent period, the provider may charge the beneficiary to the extent costs in the second preceding cost reporting period (or the equivalent when there is no second preceding period) exceed the current cost limits. (Data from the most recently submitted appropriate cost report will be used in determining the actual cost.) For example, if a limit of $58 per day is applied to the cost of general routine services for the provider's cost reporting period starting in calendar year 1975 and if the provider's actual general routine cost in the second preceding reporting period, that is, the reporting period starting in calendar year 1973, was $60 per day, the provider (after first having obtained intermediary validation and subject to the considerations and requirements specified in paragraph (a) of this section) may charge Medicare Part A beneficiaries up to $2 per day for general routine services.

(2) *Adjusting cost.* Program reimbursement for the costs to which limits imposed under § 413.30 are applied in any cost reporting period will not exceed the lesser of the provider's actual cost or the limits imposed under § 413.30. If program reimbursement for items or services to which such limits are applied plus the charges to beneficiaries for such items or services imposed under this section exceed the provider's actual cost for such items or services, program payment to the provider will be reduced to the extent program payment plus charges to the beneficiaries exceed actual cost. If the provider's actual cost for general routine services in 1975 was $57,000, the cost limit was $58,000, and billed charges to Medicare Part A beneficiaries were $2,000, the provider would receive $55,000 from the program ($57,000 actual cost minus the $2,000 in charges to the beneficiaries).

(d) *Definition of emergency services.* For purposes of paragraph (a)(2) of this section, emergency services are those hospital services that are necessary to prevent the death or serious impairment of the health of the individual, and which, because of the threat to the life or health of the individual, necessitate the use of the most accessible hospital (as determined under § 424.106 of this chapter) available and equipped to furnish such services. If an individual has been admitted to such hospital as an inpatient because of an emergency, the emergency will be deemed to continue until it is safe from a medical standpoint to move the individual to another hospital or other institution or to discharge him.

(e) *Identification of charges to individual.* For purposes of paragraph (a)(5) of this section, a provider must give or send to the individual or his representative, a schedule of all items and services that the individual might need and for which the provider imposes charges under this section, and the charge for each. Such schedule must specify that the charges are necessary to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare and include such other information as HCFA considers necessary to protect the individual's rights under this section. The provider, in arranging for the individual's admission, first service, or start of care, must give or send this schedule to the individual or his representative when arrangements are being made for such services or if this is not feasible, as soon thereafter as is practicable but no later than at the initiation of services.

[51 FR 34793, Sept. 30, 1986, as amended at 53 FR 6648, Mar. 20, 1988]

§ 413.40 Ceiling on rate of hospital cost increases.

(a) *Introduction—(1) Scope.* This section implements section 1886(b) of the Act establishing a ceiling on the rate of increase of operating costs per case for inpatient hospital services that will be recognized as reasonable for purposes of determining Medicare

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reimbursement. This ceiling on allowable rate of cost increases applies to hospital cost reporting periods beginning on or after October 1, 1982 and, for cost reporting periods beginning before October 1, 1983, is applied in addition to the limitations on reasonable cost established under § 413.30. This section also sets forth rules governing exemptions from, and exceptions and adjustments to, the ceiling.

(2) *Applicability.* (i) This section is not applicable to—

(A) Hospitals reimbursed in accordance with section 1814(b)(3) of the Act or under State reimbursement control systems that have been approved under secton 1886(c) of the Act and Subpart C of Part 403 of this chapter; or

(B) Hospitals that are paid under the prospective payment system for inpatient hospital services in accordance with section 1886(d) of the Act and Part 412 of this chapter.

(ii) For cost reporting periods beginning on or after October 1, 1983, this section is applicable to hospitals excluded from the prospective payment system in accordance with § 412.23 of this chapter, subprovider psychiatric and rehabilitation units (distinct parts) excluded from the prospective payment system in accordance with §§ 412.25 through 412.32 of this chapter, and those hospitals eligible for special treatment under the prospective payment system as described in § 412.94(b) of this chapter.

(b) *Cost reporting periods subject to the rate of increase ceiling*—(1) *Base period.* Each hospital's ceiling is based on allowable inpatient operating costs per case incurred in the 12-month cost reporting period immediately preceding the first cost reporting period subject to ceilings established under this section, except that, when the immediately preceding cost reporting period is a short reporting period (fewer than 12 months) the first 12-month period subsequent to that short period is the base period. The ceiling established under this procedure remains applicable for a hospital or excluded distinct part hospital unit, as described in §§ 412.25 through 412.32 of this chapter, in spite of intervening cost reporting periods during which the hospital or excluded distinct part hospital unit is not subject to the target amount as a result of other provisions of the law or regulations, or nonparticipation in the Medicare program, unless the hospital or excluded distinct part hospital unit qualifies as a new hospital or excluded distinct part hospital unit under paragraph (f) of this section.

(2) *Periods subject to the ceiling.* Ceilings established under this section are applied to all cost reporting periods that—

(i) Begin on or after October 1, 1982; and

(ii) Immediately follow the base period established under paragraph (b)(1) of this section unless the exception in paragraph (b)(3) of this section is applicable.

(3) *Periods other than 12 months.* Ceilings established under this section will not apply to cost reporting periods of fewer than 12 months that occur along with a change in operations of the facility as a result of changes in ownership, merger, or consolidation. However, ceilings will apply to cost reporting periods of fewer than 12 months that result solely from the approval of a hospital's request for a change in accounting cycle. In the case of such periods, the applicable percentage rate of increase will be adjusted downward by a monthly factor corresponding to the annual percentage rate to reflect fewer months. Ceilings established under this section will apply to cost reporting periods of greater than 12 months with the percentage rate of increase adjusted upward by a monthly factor corresponding to the annual percentage rate to reflect the additional months.

(c) *Procedure for establishing the ceiling (target amount)*—(1) *Costs subject to the ceiling.* (i) The cost per case ceiling established under this section applies to operating costs incurred by a hospital in furnishing inpatient hospital services.

(ii) For cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983, these operating costs *include* operating costs of routine services (as described in § 413.53(b)), ancillary service operating costs, and special care unit operating costs. These operating costs *exclude* the costs of malpractice insurance, certain kidney acquisition costs, capital-related costs, and costs a hospital allocates to approved medical education programs (nursing school or approved intern and resident programs) on its Medicare cost report.

(iii) For cost reporting periods beginning on or after October 1, 1983, these operating costs exclude only capital-related costs as described in § 413.130, return on equity capital as described in § 413.157, and the costs of approved medical education programs as described in § 413.85. Further, kidney acquisition costs incurred by hospitals approved as renal transplantation centers will be reimbursed on a reasonable cost basis. Appropriate adjustment to a hospital's base year costs will be made under paragraph (h) of this section.

(2) *Cost determined on a per case basis.* Costs subject to the ceiling as described in paragraph (c)(1) of this section will be determined on a per discharge basis.

(3) *Target rate percentage.*(i) The applicable target rate percentage is determined as follows:

(A) *Federal fiscal year 1986.* The applicable target rate percentage for cost reporting periods beginning on or after October 1, 1985 and before September 30, 1986 is five-twenty-fourths of one percent. For purposes of determining the target amount for cost reporting periods beginning on or after October 1, 1986, the applicable percentage increase with respect to cost reporting periods beginning during Federal fiscal year 1986 is deemed to have been one-half percent.

(B) *Federal fiscal year 1987.* The applicable target rate percentage for cost reporting periods beginning on or after October 1, 1986 and before September 30, 1987 is 1.15 percent.

(C) *Federal fiscal year 1988.* The applicable target rate percentage for cost reporting periods beginning on or after October 1, 1987 and before October 1, 1988 is 2.3238 percent. For purposes of updating the target rates for cost reporting periods beginning on or after October 1, 1988, the target rate percentage for cost reporting periods beginning during FY 1988 is deemed to have been 2.7 percent.

(D) *Federal fiscal year 1989 and following:* The applicable target rate percentage for cost reporting periods beginning during FY 1989 and in all fiscal years thereafter is the percentage increase in the hospital market basket (as described in paragraph (c)(3)(ii) of this section).

(ii) The market basket index is a hospital wage and price index that incorporates approximately weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in the most common categories of inpatient hospital operating costs subject to the ceiling as described in paragraph (c)(1) of this section.

(4) *Target amount (ceiling).* The intermediary will establish for each hospital a ceiling on the reimbursable costs per case of that hospital. The ceiling for each 12-month cost reporting period will be set at a target amount determined as follows:

(i) For the first 12-month cost reporting period to which this ceiling applies, the target amount will equal the hospital's allowable operating costs per case for the hospital's base period increased by the target rate percentage for the subject period.

(ii) For subsequent 12-month cost reporting periods, the target amount will equal the hospital's target amount for the previous 12-month cost reporting period increased by the target rate percentage for the subject cost reporting period.

(5) *Applicable target rate percentage.* (i) The intermediary will use the target rate percentage increase applicable to each 12-month cost reporting period to determine the ceiling on the allowable rate of cost increase under this section.

(ii) When a cost reporting period spans portions of two calendar years, the intermediary will calculate an appropriate prorated percentage rate based on the published calendar year percentage rates.

(iii) The applicable target rate percentage will be the prospectively determined percentage published by HCFA. The percentages will be applied prospectively and will be prorated in accordance with paragraph (c)(5)(ii) of this section, but will not be retroactively adjusted if the acutal market basket rate of increase differs from the estimate.

(d) *Application of target amounts in determining reimbursement*—(1) *General process.* (i) At the end of each 12-month cost reporting period subject to this section, the hospital's intermediary will compare a hospital's allowable cost per case with that hospital's target amount for that period.

(ii) The hospital's actual allowable costs will be determined without regard to the lesser of cost or charges provisions of § 413.13, but, for cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983, are subject to other limitations on reimbursable cost established under § 413.30.

(iii) If the hospital's actual allowable costs do not exceed the target amount, reimbursement will be determined under paragraph (d)(2) of this section.

(iv) If the hospital's actual costs exceed the target amount, reimbursement will be determined under paragraph (d)(3) of this section.

(2) *Inpatient operating costs are less than or equal to the target amount.* If a hospital's allowable inpatient operating costs per case do not exceed the hospital's target amount for the applicable cost reporting period, reimbursement to the hospital will be determined on the basis of the lowest of the—

(i) Inpatient operating costs per case plus 50 percent of the difference between the inpatient operating cost per case and the target amount;

(ii) Inpatient operating costs per case plus 5 percent of the target amount; or

(iii) Hospital's allowable inpatient operating cost per case under applicable limits established under § 413.30, if applicable.

(3) *Inpatient operating costs are greater than the target amount.* If a hospital's allowable inpatient operating costs per case exceed the hospital's target amount for the applicable cost reporting period, reimbursement to the hospital will be determined as follows:

(i) For cost reporting periods beginning on or after October 1, 1982 and before October 1, 1984, reimbursement will be based on the lower of the hospital's—

(A) Target amount plus 25 percent of the allowable operating costs per case in excess of the target amount; or

(B) Allowable cost per case under applicable limits established under § 413.30 if applicable.

(ii) For cost reporting periods beginning on or after October 1, 1984, reimbursement will be based on the hospital's target amount per case.

(e) *Hospital requests regarding applicability of the rate of increase ceiling.* A hospital may request an exemption from, or exception or adjustment to, the rate of cost increase ceiling imposed under this section. The hospital's request must be made to its fiscal intermediary no later than 180 days from the date on the intermediary's notice of program reimbursement. The intermediary makes a recommendation on the hospital's request to HCFA, which makes the decision. HCFA responds to the request within 180 days from the date HCFA receives the request from the intermediary. The intermediary notifies the hospital of HCFA's decision. The time required for HCFA to review the request is considered good cause for the granting of an extension of the time limit to apply for review by the Provider Reimbursement Review Board, as specified in § 405.1841(b) of this chapter. HCFA's decision is subject to review under Subpart R of Part 405 of this chapter.

(f) *Exemptions*—(1)(i) *New hospitals.* New hospitals that request and receive an exemption from HCFA are not subject to the rate of increase ceiling imposed under this section. For purposes of this section, a new hospital is a provider of inpatient hospital services that has operated as the type of hospital for which HCFA granted it approval to participate in the Medicare program, under present or previous ownership, or both, for less than three full years. This exemption expires at the end of the first cost reporting period beginning at least two years after the hospital accepts its first patient. The first cost reporting period beginning at least two years after the hospital accepts its first patient is the base period in accordance with paragraph (b) of this section.

(ii) A newly-established distinct part unit that is excluded from the prospective payment system under the provisions of §§ 412.25 through 412.32 of this chapter does not qualify for the exemption afforded to a new hospital under paragraph (f)(1)(i) of this section unless the distinct part unit is located in a hospital that, if it were subject to the provisions of this section, would qualify as a new hospital under paragraph (f)(1)(i) of this section. The first 12-month cost reporting period under which a newly-established excluded distinct part unit exists is the base period used to establish a target amount.

(2) *Risk-basis HMO.* The items or services are furnished to beneficiaries enrolled in an HMO by a hospital that is either owned or operated by a risk-basis HMO or related to a risk-basis HMO by common ownership or control (see § 417.250(c)).

(g) *Exceptions*—(1) *General procedure.* HCFA may adjust a hospital's operating costs (as described in paragraph (b)(1) of this section) upward or downward, as appropriate, under circumstances as specified in paragraphs (g)(2) and (3) of this section. HCFA makes an adjustment only to the extent that the hospital's operating costs are reasonable, attributable to the circumstances specified, separately identified by the hospital, and verified by the intermediary. HCFA may grant an exception only if a hospital's operating costs exceed the rate of increase ceiling imposed under this section.

(2) *Extraordinary circumstances.* The hospital can show that it incurred unusual costs (in either a cost reporting period subject to the ceiling or the hospital's base period) due to extraordinary circumstances beyond its control. These circumstances include, but are not limited to, strikes, fire, earthquakes, floods, or similar unusual occurrences with substantial cost effects.

(3) *Change in case mix.* The hospital—

(i) Has added or discontinued services in a year after its base period described in paragraph (b)(1) of this section;

(ii) Has experienced a change in case mix as a result of the addition or discontinuation of services that results in a distortion in the rate of cost increase; and

(iii) Submits data summarizing the case-mix changes and the resulting changes in costs.

(h) *Adjustments*—(1) *Comparability of cost reporting periods.* (i) HCFA may adjust the amount of the operating costs considered in establishing cost per case for one or more cost reporting periods, including both periods subject to the ceiling and the hospital's base period, to take into account factors that could result in a significant distortion in the operating costs of inpatient hospital services. The adjustments include, but are not limited to, adjustments of the base period costs to include explicitly FICA taxes (if the hospital did not incur costs for FICA taxes in its base period), and services billed under Part B of Medicare during the base period, but paid under Part A during the subject cost reporting period.

(ii) In determining the target amount for cost reporting periods beginning on or after October 1, 1983, the intermediary will adjust the base period costs to explicitly include in the costs subject to the ceiling malpractice insurance costs.

(iii) HCFA may adjust the amount of operating costs, under paragraph (c)(1) of this section, to take into account factors such as a change in the inpatient hospital services that a hospital provides, that are customarily provided directly by similar hospitals, or the manipulation of discharges to increase reimbursement. A change in the inpatient hospital services provided could result from changes that include, but are not limited to, opening or closing a special care unit or changing the arrangements under which such services may be furnished, such as leasing a department. HCFA may grant an adjustment only if a hospital's operating costs exceed the rate of increase ceiling imposed under this section.

(2) *Nursing differential.* Because the Medicare inpatient routine nursing salary cost differential does not apply in the cost reporting periods subject to ceilings established under this section, HCFA will adjust base period costs to remove the effect of this differential.

(i) *Target amount revisions for Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100-360)* (1) *General rule.* For cost reporting periods beginning on or after October 1, 1988, HCFA may adjust a hospital's target amount to take into account any distortion in operating costs between the hospital's base period and the period subject to the rate of increase ceiling due to the elimination of Part A inpatient hospital benefit limitations under section 101 of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100-360).

(2) *Request for adjustment.* A hospital must request an adjustment no later than 180 days after the close of its first cost reporting period beginning on or after October 1, 1988. A request for adjustment must include the following:

(i) A statement from the hospital specifying that adjustment is to be based on its historical experience in—

(A) Its base period; or

(B) Its last cost reporting period beginning before October 1, 1988. (If this period is not at least 12 months in duration, multiple consecutive cost reporting periods comprising at least 12 months must be used.)

(ii) The hospital's cost report or reports for the period selected by the hospital under paragraph (i)(2)(i) of this section to serve as the basis for the adjustment.

(iii) Billing data for the cost reporting period selected under paragraph (i)(2)(i) of this section as the basis for the adjustment documenting the following:

(A) The number of hospital inpatient days furnished to Medicare beneficiaries for which no payment was made because the beneficiary had exhausted Medicare Part A hospital benefits during an inpatient hospital stay. (Excluded from the count are days for stays that were not covered in their entirety.)

(B) The ancillary charges for services furnished on the days counted in paragraph (i)(2)(iii)(A) of this section.

(3) *Amount of adjustment.* The adjustment is based on the estimated incremental costs of care historically furnished to Medicare beneficiaries after they had exhausted their benefits during an inpatient hospital stay.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 42235, Nov. 24, 1986; 52 FR 6099, Feb. 27, 1987; 53 FR 6648, Mar. 2, 1988; 53 FR 38533, Sept. 30, 1988]

Subpart D—Apportionment

§ 413.50 Apportionment of allowable costs.

(a) Consistent with prevailing practice in which third-party organizations pay for health care on a cost basis, reimbursement under the Medicare program involves a determination of—

(1) Each provider's allowable costs for producing services; and

(2) The share of these costs which is to be borne by Medicare. The provider's costs are to be determined in accordance with the principles reviewed in the preceding discussion relating to allowable costs. The share to be borne by Medicare is to be determined in accordance with principles relating to apportionment of cost.

(b) In the study and consideration devoted to the method of apportioning costs, the objective has been to adopt methods for use under Medicare that would, to the extent reasonably possible, result in the program's share of a provider's total allowable costs being the same as the program's share of the provider's total services. This result is essential for carrying out the statutory directive that the program's payments to providers should be such that the costs of covered services for beneficiaries would not be passed on to nonbeneficiaries, nor would the cost of services for nonbeneficiaries be borne by the program.

(c) A basic factor bearing upon apportionment of costs is that Medicare beneficiaries are not a cross section of the total population. Nor will they constitute a cross section of all patients receiving services from most of the providers that participate in the program. Available evidence shows that the use of services by persons age 65 and over differs significantly from other groups. Consequently, the objective sought in the determination of the Medicare share of a provider's total costs means that the methods used for apportionment must take into account the differences in the amount of services received by patients who are beneficiaries and other patients serviced by the provider.

(d) The method of cost reimbursement most widely used at the present time by third-party purchasers of inpatient hospital care apportions a provider's total costs among groups served on the basis of the relative number of days of care used. This method, commonly referred to as average-per-diem cost, does not take into account, variations in the amount of service which a day of care may represent and thereby assumes that the patients for whom payment is made on this basis are average in their use of service.

(e) In considering the average-per-diem method of apportioning cost for use under the program, the difficulty encountered is that the preponderance of presently available evidence strongly indicates that the over-age 65 patient is not typical from the standpoint of average-per-diem cost. On the average this patient stays in the hospital twice as long and therefore the ancillary services that he uses are averaged over the longer period of time, resulting in an average-per-diem cost for the aged alone, significantly below the average-per-diem for all patients.

(f) Moreover, the relative use of services by aged patients as compared to other patients differs significantly among institutions. Consequently, considerations of equity among institutions are involved as well as that of effectiveness of the apportionment method under the program in accomplishing the objective of paying each provider fully, but only for services to beneficiaries.

(g) A further consideration of long-range importance is that the relative use of services by aged and other patients can be expected to change, possibly to a significant extent in future years. The ability of apportionment methods used under the program to reflect such change is an element of flexibility which has been regarded as important in the formulation of the cost reimbursement principles.

(h) An alternative to the relative number of days of care as a basis for apportioning costs is the relative amount of charges billed by the provider for services to patients. The amount of charges is the basis upon which the cost of hospital care is distributed among patients who pay directly for the services they receive. Payment for services on the basis of charges applies generally under insurance programs in which individuals are indemnified for incurred expenses, a form of health insurance widely held throughout the United States. Also, charges to patients are commonly a factor in determining the amount of payment to hospitals under insurance programs providing service benefits, many of which pay "costs or charges, whichever is less" and some of which pay exclusively on the basis of charges. In all of these instances, the provider's own charge structure and method of itemizing services for the purpose of assessing charges is utilized as a measure of the amount of services received and as the basis for allocating responsibility for payment among those receiving the provider's services.

(i) An increasing number of third-party purchasers who pay for services on the basis of cost are developing methods that utilize charges to measure the amount of services for which they have responsibility for payment. In this approach, the amount of charges for such services as a proportion of the provider's total charges to all patients is used to determine the proportion of the provider's total costs for which the third-party purchaser assumes responsibility. The approach is subject to numerous variations. It can be applied to the total of charges for all services combined or it can be applied to components of the provider's activities for which the amount of costs and charges are ascertained through a breakdown of data from the provider's accounting records.

(j) For the application of the approach to components, which represent types of services, the breakdown of total costs is accomplished by "cost-finding" techniques under which indirect costs and nonrevenue activities are allocated to revenue producing components for which charges are made as services are furnished.

§ 413.53 Determination of cost of services to beneficiaries.

(a) *Principle.* Total allowable costs of a provider will be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries. The methods of apportionment are defined as follows:

(1) *Departmental method*—(i) *Methodology.* Except as provided in § 413.56 with respect to the direct apportionment of malpractice costs, and in paragraph (a)(1)(ii) of this section with respect to the treatment of the private room cost differential for cost reporting periods starting on or after October 1, 1982, the ratio of beneficiary charges to total patient charges for the services of each ancillary department is applied to the cost of the department; to this is added the cost of routine services for program beneficiaries, determined on the basis of a separate average cost per diem for general routine patient care areas as defined in paragraph (b) of this section, taking into account, in hospitals, a separate average cost per diem for each intensive care unit, coronary care unit, and other intensive care type inpatient hospital units.

(ii) *Exception: Indirect cost of private rooms.* For cost reporting periods starting on or after October 1, 1982, except with respect to a hospital receiving payment under Part 412 of this chapter, the additional cost of furnishing services in private room accommodations is apportioned to Medicare only if these accommodations are furnished to program beneficiaries, and are medically necessary. To determine routine service cost applicable to beneficiaries—

(A) Multiply the average cost per diem (as defined in paragraph (b) of this section) by the total number of Medicare patient days (including private room days whether or not medically necessary);

(B) Add the product of the average per diem private room cost differential (as defined in paragraph (b) of this section) and the number of medically necessary private room days used by beneficiaries; and

(C) Do not include private rooms furnished for SNF-type and ICF-type services under the swing-bed provision in the number of days in paragraphs (a)(1)(ii) (A) and (B) of this section.

(2) *Carve out method.* (i) The carve out method is used to allocate hospital inpatient general routine service costs in a participating swing-bed hospital, as defined in § 413.114(b). Under this method, the total costs attributable to the SNF-type and ICF-type services furnished to all classes of patients are subtracted from total general routine inpatient service costs before computing the average cost per diem for general routine hospital care.

(ii) The cost per diem attributable to the routine SNF-type services furnished by a swing-bed hospital is based on the reasonable cost per diem for services determined in accordance with § 413.114.

(iii) The cost per diem attributable to the routine ICF services furnished by the swing-bed hospital is determined as follows:

(A) If the hospital is located in a State that provides for ICF services under Medicaid, the cost per diem for ICF services furnished by a swing-bed hospital in that State is based on the Statewide average rate paid for routine services in ICFs (other than ICFs for the mentally retarded) during the preceding calendar year under the State Medicaid plan. The Statewide average rate will be computed either by the State and furnished to HCFA, or by HCFA directly based on the best available data.

(B) If the hospital is located in a State that does not provide for ICF services under Medicaid or that does not have a Medicaid program, the cost per diem for ICF services will be based on the average ratio of the ICF rate to the SNF rate in those States that provide for both SNF and ICF services under Medicaid. The ratio will be applied to the SNF cost per diem determined under paragraph (a)(2)(ii) of this section.

(iv) The sum of total SNF-type days furnished to all classes of patients multiplied by the SNF cost per diem, and total ICF-type days furnished to all classes of patients multiplied by the appropriate ICF cost per diem, will be subtracted from inpatient general routine service costs. The cost per diem for inpatient general routine hospital care will be based on the remaining general routine service costs.

(v) Costs other than general inpatient routine service costs will be determined in the same manner as specified in the Departmental Method in paragraph (a)(1) of this section.

(3) *Cost per visit by type-of-service method—HHAs.* For cost reporting periods beginning on or after October 1, 1980, all HHAs must use the cost per visit by type-of-service method of apportioning costs between Medicare and non-Medicare beneficiaries. Under this method, the total allowable cost of all visits for each type of service is divided by the total number of visits for that type of service. Next, for each type of service, the number of Medicare covered visits is multiplied by the average cost per visit just computed. This represents the cost Medicare will recognize as the cost for that service, subject to cost limits published by HCFA (see § 413.30).

(b) *Definitions.* As used in this section—

"Ancillary services" means the services for which charges are customarily made in addition to routine services.

"Apportionment" means an allocation or distribution of allowable cost between the beneficiaries of the Medicare program and other patients.

"Average cost per diem for general routine services" means the following:

(1) For cost reporting periods beginning on or after October 1, 1982, subject to the provisions on swing-bed hospitals, the average cost of general routine services net of the private room cost differential. The average cost per diem is computed by the following methodology:

(i) Determine the total private room cost differential by multiplying the average per diem private room cost differential determined in paragraph (c) of this section by the total number of private room patient days.

(ii) Determine the total inpatient general routine service costs net of the total private room cost differential by subtracting the total private room cost differential from total inpatient general routine service costs.

(iii) Determine the average cost per diem by dividing the total inpatient general routine service cost net of private room cost differential by all inpatient general routine days, including total private room days.

(2) For swing-bed hospitals, the amount computed by—(i) Subtracting the costs attributable to SNF-type and ICF-type services from the total allowable inpatient cost for routine services (excluding the cost of services provided in intensive care units, coronary care units, and other intensive care type inpatient hospital units, and nursery costs); And (ii) dividing the remainder (excluding the total private room cost differential) by the total number of inpatient hospital days of care (excluding SNF-type and ICF-type days of care, days of care in intensive care units, coronary care units, and other intensive care type inpatient hospital units, and newborn days and including total private room days).

"Average cost per diem for hospital intensive care type units" means the amount computed by dividing the total allowable costs for routine services in each of these units by the total number of inpatient days of care furnished in each of these units.

"Average per diem private room cost differential" means the difference in the average per diem cost of furnishing routine services in a private room and in a semi-private room. (This differential is not applicable to hospital intensive care type units.) (The method for computing this differential is described in paragraph (c) of this section.)

"Charges" means the regular rates for various services that are charged to both beneficiaries and other paying patients who receive the services. Implicit in the use of charges as the basis for apportionment is the objective that charges for services be related to the cost of the services.

"ICF-type services" means routine services furnished by a swing-bed hospital that would constitute intermediate care facility (ICF) services, as defined in § 440.150 of this chapter, if furnished by an ICF. ICF-type services are not covered under the Medicare program.

"Intensive care type inpatient hospital unit" means a hospital unit that furnishes services to critically ill inpatients. Examples of intensive care type units include, but are not limited to, intensive care units, trauma units, coronary care units, pulmonary care units, and burn units. Excluded as intensive care type units are postoperative recovery rooms, postanesthesia recovery rooms, maternity labor rooms, and subintensive or intermediate care units. (The unit must also meet the criteria of paragraph (d) of this section.)

"SNF-type services" means routine services furnished by a swing-bed hospital that would constitute extended care services if furnished by an SNF. SNF-type services include routine services furnished in the distinct part SNF of a hospital complex that is combined with the hospital general routine service area cost center under § 413.24(d)(5).

"Ratio of beneficiary charges to total charges on a departmental basis" means the ratio of charges to beneficiaries of the Medicare program for services of a revenue-producing department or center to the charges to all patients for that center during an accounting period. After each revenue-producing center's ratio is determined, the cost of services furnished to beneficiaries of the Medicare program is computed by applying the individual ratio for the center to the cost of the related center for the period.

"Routine services" means the regular room, dietary, and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.

(c) *Method for computing the average per diem private room cost differential.* Compute the average per diem private room cost differential as follows:

(1) Determine the average per diem private room charge differential by subtracting the average per diem charge for all semi-private room accommodations from the average per diem charge for all private room accommodations. The average per diem charge for private room accommodations is determined by dividing the total charges for private room accommodations by the total number of days of care furnished in private room accommodations. The average per diem charge for semi-private accommodations is determined by dividing the total charges for semi-private room accommodations by the total number of days of care furnished in semi-private accommodations.

(2) Determine the inpatient general routine cost to charge ratio by dividing total inpatient general routine service cost by the total inpatient general routine service charges.

(3) Determine the average per diem private room cost differential by multiplying the average per diem private room charge differential determined in paragraph (c)(1) of this section by the ratio determined in paragraph (c)(2) of this section.

(d) *Criteria for identifying intensive care type units.* For purposes of determining costs under this section, a unit will be identified as an intensive care type inpatient hospital unit only if the unit—

(1) Is in a hospital;

(2) Is physically and identifiably separate from general routine patient care areas, including subintensive or intermediate care units, and ancillary service areas. There cannot be a concurrent sharing of nursing staff between an intensive care type unit and units or areas furnishing different levels or types of care. However, two or more intensive care type units that concurrently share nursing staff can be reimbursed as one combined intensive care type unit if all other criteria are met. Float nurses (nurses who work in different units on an as-needed basis) can be utilized in the intensive care type unit. If a float nurse works in two different units during the same eight hour shift, then the costs must be allocated to the appropriate units depending upon the time spent in those units. The hospital must maintain adequate records to support the allocation. If such records are not available, then the costs must be allocated to the general routine services cost areas;

(3) Has specific written policies that include criteria for admission to, and discharge from, the unit;

(4) Has registered nursing care available on a continuous 24-hour basis with at least one registered nurse present in the unit at all times;

(5) Maintains a minimum nurse-patient ratio of one nurse to two patients per patient day. Included in the calculation of this nurse-patient ratio are registered nurses, licensed vocational nurses, licensed practical nurses, and nursing assistants who provide patient care. Not included are general support personnel such as ward clerks, custodians, and housekeeping personnel; and

(6) Is equipped, or has available for immediate use, life-saving equipment necessary to treat the critically ill patients for which it is designed. This equipment may include, but is not limited to, respiratory and cardiac monitoring equipment, respirators, cardiac defibrillators, and wall or canister oxygen and compressed air.

(e) *Application*—(1) *Departmental method; Cost reporting periods beginning on or after October 1, 1982.*

(i) The following example illustrates how costs would be determined, using only inpatient data, for cost reporting periods beginning on or after October 1, 1982, based on apportionment of—

(A) The average cost per diem for general routine services (subject to the private room differential provisions of paragraph (a)(1)(iii) of this section);

(B) The average cost per diem for each intensive care type unit;

(C) The ratio of beneficiary charges to total charges applied to cost by department.

HOSPITAL Y

Department	Charges to program beneficiaries	Total charges	Ratio of beneficiary charges to total charges	Total cost	Cost of beneficiary services
			Percent		
Operating rooms	$20,000	$70,000	$28\frac{4}{7}$	$77,000	$22,000
Delivery rooms	0	12,000	0	30,000	0
Pharmacy	20,000	60,000	$33\frac{1}{3}$	45,000	15,000
X-ray	24,000	100,000	24	75,000	18,000
Laboratory	40,000	140,000	$28\frac{4}{7}$	98,000	28,000
Others	6,000	30,000	20	25,000	5,000
Total	110,000	412,000		350,000	88,000

	Total inpatient days	Total cost	Average cost per diem	Program in patient days	Cost of beneficiary services
General routine	30,000	$630,000	$21	8,000	$168,000
Coronary care unit	500	20,000	40	200	8,000
Intensive care unit	3,000	108,000	36	1,000	36,000
	33,500	758,000		9,200	212,000
Total					300,000

(ii) The following illustrates how apportionment based on an average cost per diem for general routine services is determined.

HOSPITAL E

Facts	Private accommodations	Semi-private accommodations	Total
Total charges	$20,000	$175,000	$195,000
Total days	100	1,000	1,100
Programs days	70	400	470

HOSPITAL E—Continued

Facts	Private accommodations	Semi-private accommodations	Total
Medically necessary for program beneficiaries	20		20
Total general routine service costs			165,000
Average private room per diem charge ($20,000 private room charges ÷ 100 days)			[1] $200
Average semi-private room per diem charge ($175,000 semi-private charge ÷ 1,000 days)			[1] $175

[1] Per diem.

Average per diem private room cost differential.

1. Average per diem private room charge differential ($200 private room per diem—$175, semi-private room per diem), $25.
2. Inpatient general routine cost/charge ratio ($165,000 total costs ÷ $195,000 total charges), 0.8461538.
3. Average per diem private room cost differential ($25 charge differential × .8461538 cost/charge ratio), $21.15.

Average cost per diem for inpatient general routine services.

4. Total private room cost differential ($21.15 average per diem cost differential × 100 private room days), $2,115.
5. Total inpatient general routine service costs net of private room cost differential ($165,000 total routine cost −$2,115 private room cost differential), $162,885.
6. Average cost per diem for inpatient general routine services ($162,885 routine cost net of private room cost differential ÷ 1,100 patient days), $148.08.

Medicare general routine service cost.

7. Total routine per diem cost applicable to Medicare ($148.08 average cost per diem × 470 Medicare private and semi-private patient days), $69,598.
8. Total private room cost differential applicable to Medicare ($21.15 average per diem private room cost differential × 20 medically necessary private room days), $423.
9. Medicare inpatient general routine service cost ($423 Medicare private room cost differential + $69,598 Medicare cost of general routine inpatient services), $70,021.

(2) *Carve out method.* The following illustrates how apportionment is determined in a hospital reimbursed under the carve out method (subject to the private room differential provisions of paragraph (a)(1)(ii) of this section):

HOSPITAL K

[Determination of cost of routine SNF-type and ICF-type services and general routine hospital services[1]]

Facts	Days of care		
	General routine hospital	SNF-type	ICF-type
Total days of care	2,000	400	100
Medicare days of care	600	300	
Average Medicaid rate	N/A	$35	$20
Total inpatient general routine service costs: $250,000			

Calculation of cost of routine SNF-type services applicable to Medicare:

$35 × 300 = $10,500

Calculation of cost of general routine hospital services:

Cost of SNF-type services: $35 × 400 .... $14,000
Cost of ICF-type services: $20 × 100 2,000

Total $16,000

Average cost per diem of general routine hospital services:

$250,000 — $16,000 ÷ 2,000 days = $117

Medicare general routine hospital cost:

$117 × 600 = $70,200

Total Medicare reasonable cost for general routine inpatient days:

$10,500 + $70,200 = $80,700

[51 FR 34793, Sept. 30, 1986]

§ 413.56 Malpractice insurance costs.

(a) *Apportionment of malpractice insurance premiums and self-insurance fund contributions.* For cost reporting periods beginning on or after July 1, 1979, malpractice insurance costs must be apportioned as set forth in this section. Subject to the rules of administrative finality and reopening as set forth in Subpart R of this part, hospital malpractice insurance premiums and self-insurance fund contributions must be separately accumulated and directly apportioned to Medicare based on the methodology described in paragraph (b) of this section. Allowable malpractice insurance costs of SNFs must be apportioned to Medicare based on the methodology described in paragraph (c) of this section. For purposes of this section, "premium" includes contributions to malpractice self insurance funds.

(b) *Hospital malpractice insurance cost methodology.* (1) *Components of the premium.* The premium is divided into an administrative component and a risk component as follows:

(i) The administrative component consists of 8.5 percent of the total premium amount, and accounts for an insurer's fixed overhead expenses and a proportionate share of premium and payroll taxes and commissions paid to insurance agents.

(ii) The risk component consists of 91.5 percent of the total premium amount, and accounts for an insurer's anticipated loss experience, expenses associated with losses (including defense costs and claims department overhead costs), and the remaining share of taxes and commissions paid to insurance agents that are not included in the administrative component.

(2) *Apportionment of administrative component.* The administrative component of the premium is reported as an administrative and general cost and apportioned in accordance with § 413.53(a)(1).

(3) *Apportionment of risk component.* (i) The risk component of the premium is apportioned based on a scaling factor, derived from the scaling factor formula described in paragraph (b)(3)(ii) of this section, which accounts for the hospital's Medicare utilization rate and the disproportionately low national ratio of hospital malpractice losses paid to Medicare beneficiaries, as compared to losses paid to all patients. The scaling factor is multiplied by 91.5 percent of the hospital's malpractice insurance premium to determine Medicare's share of the risk component of the premium.

(ii) The scaling factor is derived from the following formula:

$$\frac{u \times (R/U_1)}{[u \times (R/U_1)] + [(1-u) \times (1-R)/(1-U_2)]}$$

U_1 = The national Medicare hospital patient utilization rate, as adjusted for the time lag between incident and claim closure for Medicare patients.

U_2 = The national Medicare hospital patient utilization rate, as adjusted for the time lag between incident and claim closure for non-Medicare patients.

R = The national Medicare malpractice loss ratio, as adjusted for associated claims handling expense.

u = The hospital's own Medicare utilization rate for the cost reporting period based on a ratio of the hospital's total Medicare-covered inpatient days of care to its total inpatient days of care.

R/U_1 = The national Medicare malpractice loss ratio compared to the national Medicare utilization rate.

$(1-R)/(1-U_2)$ = The national non-Medicare malpractice loss ratio compared to the national non-Medicare utilization rate.

(4) *Example:* Apportionment of Medicare's share of the malpractice insurance costs of a hospital that averages 75 percent Medicare utilization during the applicable cost reporting period is calculated as follows:

Step one—The administrative component of the premium (8.5 percent) is included in the administrative and general cost center of the hospital and is apportioned on a utilization basis. This, the hospital would be reimbursed approximately .085 times .75, or 6.38 percent of the administrative component of its premium. (This figure would vary slightly depending upon the hospital's specific Medicare utilization of its patient care departments.)

Step two—The risk component of the premium (91.5 percent) is apportioned on a basis which accounts for the hospital's own Medicare patient utilization rate and the adjusted national Medicare malpractice loss ratio by multiplying 91.5 percent by the .421 scaling factor derived from the scaling factor formula, as follows:

u = 75.0 percent
R = 13.2 percent
U_1 = 38.8 percent
U_2 = 38.1 percent

$$\frac{.75 \times (.132/.388)}{[.75 \times (.132/.388)] + [(1-.75) \times (1-.132)/(1-.381)]} = .421$$

Thus, the hospital would be reimbursed .915 times .421, or 38.54 percent of the risk component of its premium. This means that Medicare reimbursement would account for 6.38 percent plus 38.54 percent, or 44.92 percent of this hospital's total malpractice insurance premium.

(5) *Updating of factors used in determining apportionment.* Based on actual cost reports data, HCFA will pe-

riodically calculate the national average of Medicare utilization and the national ratio of hospital malpractice losses paid to Medicare beneficiaries to malpractice losses paid to all hospital patients. Periodically, as warranted by changes in these factors, HCFA will—

(i) Publish a notice in the FEDERAL REGISTER describing the proposed changes for public comment; and

(ii) In a subsequent FEDERAL REGISTER notice, update the relevant factors and respond to comments.

(6) *Allowable uninsured malpractice losses and related direct costs incurred by a hospital.* If a hospital pays an allowable uninsured malpractice loss to or on behalf of a Medicare beneficiary in order to comply with a deductible or coinsurance provision of its malpractice insurance policy, or as a result of an award in excess of a reasonable coverage limit, or as a governmental provider, that loss and related direct costs must be directly assigned to Medicare for reimbursement. An uninsured malpractice loss paid to or on behalf of a non-Medicare patient is not an allowable cost.

(c) *SNF malpractice insurance cost methodology.* Costs of malpractice insurance premiums and self-insurance fund contributions, in addition to other allowable malpractice insurance costs of an SNF, are reported as an administrative and general cost and apportioned in accordance with § 413.53(a)(1).

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986]

Subpart E—Payments to Providers

§ 413.60 Payments to providers: General.

(a) The fiscal intermediaries will establish a basis for interim payments to each provider. This may be done by one of several methods. If an intermediary is already paying the provider on a cost basis, the intermediary may adjust its rate of payment to an estimate of the result under the Medicare principles of reimbursement. If no organization is paying the provider on a cost basis, the intermediary may obtain the previous year's financial statement from the provider and, by applying the principles of reimbursement, compute or approximate an appropriate rate of payment. The interim payment may be related to the last year's average per diem, or to charges, or to any other ready basis of approximating costs.

(b) At the end of the period, the actual apportionment, based on the cost finding and apportionment methods selected by the provider, determines the Medicare reimbursement for the actual services provided to beneficiaries during the period.

(c) Basically, therefore, interim payments to providers will be made for services throughout the year, with final settlement on a retroactive basis at the end of the accounting period. Interim payments will be made as often as possible and in no event less frequently than once a month. The retroactive payments will take fully into account the costs that were actually incurred and settle on an actual, rather than on an estimated basis.

§ 413.64 Payments to providers: Specific rules.

(a) *Reimbursement on a reasonable cost basis.* Providers of services paid on the basis of the reasonable cost of services furnished to beneficiaries will receive interim payments approximating the actual costs of the provider. These payments will be made on the most expeditious schedule administratively feasible but not less often than monthly. A retroactive adjustment based on actual costs will be made at the end of a reporting period.

(b) *Amount and frequency of payment.* Medicare states that providers of services will be paid the reasonable cost of services furnished to beneficiaries. Since actual costs of services cannot be determined until the end of the accounting period, the providers must be paid on an estimated cost basis during the year. While Medicare provides that interim payments will be made no less often than monthly, intermediaries are expected to make payments on the most expeditious basis administratively feasible. Whatever estimated cost basis is used for determining interim payments during the year, the intent is that the interim payments shall approximate actual costs as nearly as is practicable so that the retroactive adjustment based on actual costs will be as small as possible.

(c) *Interim payments during initial reporting period.* At the beginning of the program or when a provider first participates in the program, it will be necessary to establish interim rates of payment to providers of services. Once a provider has filed a cost report under the Medicare program, the cost report may be used as a basis for determining the interim rate of reimbursement for the following period. However, since initially there is no previous history of cost under the program, the interim rate of payment must be determined by other methods, including the following:

(1) If the intermediary is already paying the provider on a cost or cost-related basis, the intermediary will adjust its rate of payment to the program's principles of reimbursement. This rate may be either an amount per inpatient day, or a percent of the provider's charges for services furnished to the program's beneficiaries.

(2) If an organization other than the intermediary is paying the provider for services on a cost or cost-related basis, the intermediary may obtain from that organization or from the provider itself the rate of payment being used and other cost information as may be needed to adjust that rate of payment to give recognition to the program's principles of reimbursement.

(3) It no organization is paying the provider on a cost or cost-related basis, the intermediary will obtain the previous year's financial statement from the provider. By analysis of such statement in light of the principles of reimbursement, the intermediary will compute an appropriate rate of payment.

(4) After the initial interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the intermediary that costs have increased. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(d) *Interim payments for new providers.* (1) Newly-established providers will not have cost experience on which to base a determination of an interim rate of payment. In such cases, the intermediary will use the following methods to determine an appropriate rate:

(i) If there is a provider or providers comparable in substantially all relevant factors to the provider for which the rate is needed, the intermediary will base an interim rate of payment on the costs of the comparable provider.

(ii) If there are no substantially comparable providers from whom data are available, the intermediary will determine an interim rate of payment based on the budgeted or projected costs of the provider.

(2) Under either method, the intermediary will review the provider's cost experience after a period of three months. If need for an adjustment is indicated, the interim rate of payment will be adjusted in line with the provider's cost experience.

(e) *Interim payments after initial reporting period.* Interim rates of payment for services provided after the initial reporting period will be established on the basis of the cost report filed for the previous year covering Medicare services. The current rate will be determined—whether on a per diem or percentage of charges basis—using the previous year's costs of covered services and making any appropriate adjustments required to bring, as closely as possible, the current year's rate of interim payment into agreement with current year's costs. This interim rate of payment may be adjusted by the intermediary during an accounting period if the provider submits appropriate evidence that its actual costs are or will be significantly higher than the computed rate. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(f) *Retroactive adjustment.* (1) Medicare provides that providers of services will be paid amounts determined to be due, but not less often than monthly, with necessary adjustments due to previously made overpayments or underpayments. Interim payments are made on the basis of estimated costs. Actual costs reimbursable to a provider cannot be determined until the cost reports are filed and costs are verified. Therefore, a retroactive adjustment will be made at the end of the reporting period to bring the interim payments made to the provider during the period into agreement with the reimbursable amount payable to the provider for the services furnished to program beneficiaries during that period.

(2) In order to reimburse the provider as quickly as possible, an initial retroactive adjustment will be made as soon as the cost report is received. For this purpose, the costs will be accepted as reported, unless there are obvious errors or inconsistencies, subject to later audit. When an audit is made and the final liability of the program is determined, a final adjustment will be made.

(3) To determine the retroactive adjustment, the amount of the provider's total allowable cost apportioned to the program for the reporting year is computed. This is the total amount of reimbursement the provider is due to receive from the program and the beneficiaries for covered services furnished during the reporting period. The total of the interim payments made by the program in the reporting year and the deductibles and coinsurance amounts receivable from beneficiaries is computed. The difference between the reimbursement due and the payments made is the amount of the retroactive adjustment.

(g) *Accelerated payments to providers.* Upon request, an accelerated payment may be made to a provider of services that is not receiving periodic interim payments under paragraph (h) of this section if the provider has experienced financial difficulties due to a delay by the intermediary in making payments or in exceptional situations, in which the provider has experienced a temporary delay in preparing and submitting bills to the intermediary beyond its normal billing cycle. Any such payment must be approved first by the intermediary and then by HCFA. The amount of the payment is computed as a percentage of the net reimbursement for unbilled or unpaid covered services. Recovery of the accelerated payment may be made by recoupment as provider bills are processed or by direct payment.

(h) *Periodic interim payment method of reimbursement.* (1) In addition to the other methods of interim payment on individual provider billings for covered services, effective with claims received on or after July 1, 1987, the periodic interim payment (PIP) method is available for the following:

(i) Part A inpatient hospital services furnished in hospitals that are excluded from the prospective payment system under Subpart B of Part 412 of this chapter.

(ii) Part A services furnished in hospitals receiving payment in accordance with a demonstration project authorized under section 402(a) of Pub. L. 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Pub. L. 92-603 (42 U.S.C. 1395b-1 (note)), or a State reimbursement control system approved under section 1886(c) of the Act and Subpart C of Part 403 of this chapter, if that type of payment is specifically approved by HCFA as an integral part of the demonstration or control system. If that type of payment is not an integral part of the demonstration or control system, PIP is available for the hospital under paragraph (h)(1)(i) of this section for hospitals excluded from the prospective payment system or under § 412.116(b) of this chapter for prospective payment hospitals.

(iii) Part A SNF services.

(iv) Part A and Part B HHA services.

(2) Any participating provider furnishing the services described in paragraph (h)(1) of this section that establishes to the satisfaction of the intermediary that it meets the following requirements may elect to be reimbursed under the PIP method, beginning with the first month after its request that the intermediary finds administratively feasible:

(i) The provider's estimated total Medicare reimbursement for inpatient services is at least $25,000 a year computed under the PIP formula or, in the case of an HHA, either its estimated—

(A) Total Medicare reimbursement for Part A and Part B services is at least $25,000 a year computed under the PIP formula; or

(B) Medicare reimbursement computed under the PIP formula is at least 50 percent of estimated total allowable cost.

(ii) The provider has filed at least one completed Medicare cost report accepted by the intermediary as providing an accurate basis for computation of program payment (except in the case of a provider requesting reimbursement under the PIP method upon first entering the Medicare program).

(iii) The provider has the continuing capability of maintaining in its records the cost, charge, and statistical data needed to accurately complete a Medicare cost report on a timely basis.

(iv) The provider has repaid or agrees to repay any outstanding current financing payment in full, such payment to be made before the effective date of its requested conversion from a regular interim payment method to the PIP method.

(3) No conversion to the PIP method may be made with respect to any provider until after that provider has repaid in full its outstanding current financing payment.

(4) The intermediary's approval of a provider's request for reimbursement under the PIP method will be conditioned upon the intermediary's best judgment as to whether payment can be made to the provider under the PIP method without undue risk of its resulting in an overpayment because of greatly varying or substantially declining Medicare utilization, inadequate billing practices, or other circumstances. The intermediary may terminate PIP reimbursement to a provider at any time it determines that the provider no longer meets the qualifying requirements or that the provider's experience under the PIP method shows that proper payment cannot be made under this method.

(5) Payment will be made biweekly under the PIP method unless the provider requests a longer fixed interval (not to exceed one month) between payments. The payment amount will be computed by the intermediary to approximate, on the average, the cost of covered inpatient or home health services furnished by the provider during the period for which the payment is to be made, and each payment will be made two weeks after the end of such period of services. Upon request, the intermediary will, if feasible, compute the provider's payments to recognize significant seasonal variation in Medicare utilization of services on a quarterly basis starting with the beginning of the provider's reporting year.

(6) A provider's PIP amount may be appropriately adjusted at any time if the provider presents or the intermediary otherwise obtains evidence relating to the provider's costs or Medicare utilization that warrants such adjustment. In addition, the intermediary will recompute the payment immediately upon completion of the desk review of a provider's cost report and also at regular intervals not less often than quarterly. The intermediary may make a retroactive lump sum interim payment to a provider, based upon an increase in its PIP amount, in order to bring past interim payments for the provider's current cost reporting period into line with the adjusted payment amount. The objective of intermediary monitoring of provider costs and utilization is to assure payments approximating, as closely as possible, the reimbursement to be determined at settlement for the cost reporting period. A significant factor in evaluating the amount of the payment in terms of the realization of the projected Medicare utilization of services is the timely submittal to the intermediary of completed admission and billing forms. All providers must complete billings in detail under this method as under regular interim payment procedures.

(i) *Bankruptcy or insolvency of provider.* If on the basis of reliable evidence, the intermediary has a valid basis for believing that, with respect to a provider, proceedings have been or will shortly be instituted in a State or Federal court for purposes of determining whether such provider is insolvent or bankrupt under an appropriate State or Federal law, any payments to the provider will be adjusted by the intermediary, notwithstanding any other regulation or program instruction regarding the timing or manner of such adjustments, to a level necessary to insure that no overpayment to the provider is made.

(j) *Interest payments resulting from judicial review*—(1) *Application*. If a provider of services seeks judicial review by a Federal court (see § 405.1877 of this chapter) of a decision furnished by the Provider Reimbursement Review Board or subsequent reversal, affirmation, or modification by the Secretary, the amount of any award of such Federal court will be increased by interest payable by the party against whom the judgment is made (see § 413.153 for treatment of interest). The interest is payable for the period beginning on the first day of the first month following the 180-day period which began on either the date the intermediary made a final determination or the date the intermediary would have made a final determination had it been done on a timely basis (see §§ 405.1835(b) and 405.1841(a) of this chapter).

(2) *Amount due*. Section 1878(f) of the Act, 42 U.S.C. 1395oo(f), authorizes a court to award interest in favor of the prevailing party on any amount due as a result of the court's decision. If the intermediary withheld any portion of the amount in controversy prior to the date the provider seeks judicial review by a Federal court, and the Medicare program is the prevailing party, interest is payable by the provider only on the amount not withheld. Similarly, if the Medicare program seeks to recover amounts previously paid to a provider, and the provider is the prevailing party, interest on the amounts previously paid to a provider is not payable by the Medicare program since that amount had been paid and is not due the provider.

(3) *Rate*. The amount of interest to be paid is equal to the rate of return on equity capital (see § 413.157) in effect for the month in which the civil action is commenced.

Example: An intermediary made a final determinaton on the amount of Medicare program reimbursement on June 15, 1974, and the provider appealed that determination to the Provider Reimbursement Review Board. The Board heard the appeal and rendered a decision adverse to the provider. On October 28, 1974, the provider commenced civil action to have such decision reviewed. The rate of return on equity capital for the month of October 1974 was 11.625 percent. The period for which interest is computed begins on January 1, 1975, and the interest beginning January 1, 1975, would be at the rate of 11.625 percent per annum.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 42238, Nov. 24, 1986; 53 FR 1628, Jan. 21, 1988]

§ 413.74 Payment to a foreign hospital.

(a) *Principle*. Section 1814(f) of the Act provides for the payment of emergency and nonemergency inpatient hospital services furnished by foreign hospitals to Medicare beneficiaries. Subpart H of Part 424 of this chapter, together with this section, specify the conditions for payment. These conditions may result in payments only to Canadian and Mexican hospitals.

(b) *Amount of payment*. Effective with admissions on or after January 1, 1980, the reasonable cost for services covered under the Medicare program furnished to beneficiaries by a foreign hospital will be equal to 100 percent of the hospital's customary charges (as defined in § 413.13(b)) for the services.

(c) *Submittal of claims*. The hospital must establish its customary charges for the services by submitting an itemized bill with each claim it files in accordance with its election under § 424.104 of this chapter.

(d) *Exchange rate*. Payment to the hospital will be subject to the official exchange rate on the date the patient is discharged and to the applicable deductible and coinsurance amounts described in §§ 409.80 through 409.83.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart F—Specific Categories of Costs

§ 413.80 Bad debts, charity, and courtesy allowances.

(a) *Principle*. Bad debts, charity, and courtesy allowances are deductions from revenue and are not to be included in allowable cost; however, bad debts attributable to the deductibles and coinsurance amounts are reimbursable under the program.

(b) *Definitions*—(1) *Bad debts.* Bad debts are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services. "Accounts receivable" and "notes receivable" are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future.

(2) *Charity allowances.* Charity allowances are reductions in charges made by the provider of services because of the indigence or medical indigence of the patient. Cost of free care (uncompensated services) furnished under a Hill-Burton obligation are considered as charity allowances.

(3) *Courtesy allowances.* Courtesy allowances indicate a reduction in charges in the form of an allowance to physicians, clergy, members of religious orders, and others as approved by the governing body of the provider, for services received from the provider. Employee fringe benefits, such as hospitalization and personnel health programs, are not considered to be courtesy allowances.

(c) *Normal accounting treatment: Reduction in revenue.* Bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services. Such costs have already been incurred in the production of the services.

(d) *Requirements for Medicare.* Under Medicare, costs of covered services furnished beneficiaries are not to be borne by individuals not covered by the Medicare program, and conversely, costs of services provided for other than beneficiaries are not to be borne by the Medicare program. Uncollected revenue related to services furnished to beneficiaries of the program generally means the provider has not recovered the cost of services covered by that revenue. The failure of beneficiaries to pay the deductible and coinsurance amounts could result in the related costs of covered services being borne by other than Medicare beneficiaries. To assure that such covered service costs are not borne by others, the costs attributable to the deductible and coinsurance amounts that remain unpaid are added to the Medicare share of allowable costs. Bad debts arising from other sources are not allowable costs.

(e) *Criteria for allowable bad debt.* A bad debt must meet the following criteria to be allowable:

(1) The debt must be related to covered services and derived from deductible and coinsurance amounts.

(2) The provider must be able to establish that reasonable collection efforts were made.

(3) The debt was actually uncollectible when claimed as worthless.

(4) Sound business judgment established that there was no likelihood of recovery at any time in the future.

(f) *Charging of bad debts and bad debt recoveries.* The amounts uncollectible from specific beneficiaries are to be charged off as bad debts in the accounting period in which the accounts are deemed to be worthless. In some cases an amount previously written off as a bad debt and allocated to the program may be recovered in a subsequent accounting period; in such cases the income therefrom must be used to reduce the cost of beneficiary services for the period in which the collection is made.

(g) *Charity allowances.* Charity allowances have no relationship to beneficiaries of the Medicare program and are not allowable costs. These charity allowances include the costs of uncompensated services furnished under a Hill-Burton obligation. (Note: In accordance with section 106(b) of Pub. L. 97-248 (enacted September 3, 1982), this sentence is effective with respect to any costs incurred under Medicare except that it does not apply to costs which have been allowed prior to September 3, 1982, pursuant to a final court order affirmed by a United States Court of Appeals.) The cost to the provider of employee fringe-benefit programs is an allowable element of reimbursement.

§ 413.85 Cost of educational activities.

(a) *Reimbursement*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, a provider's allowable cost may include its net cost of approved educational activities, as calculated under paragraph (g) of this section.

(2) *Limit applicable to cost reporting periods beginning on or after July 1, 1985 but before July 1, 1986.* (i) For cost reporting periods beginning on or after July 1, 1985 but before July 1, 1986, a provider's net cost of approved educational activities, as calculated under paragraph (g) of this section, incurred during a cost reporting period is limited, under the authority of section 1861(v)(1)(A) of the Act, to the lesser of the provider's net cost of its program—

(A) For that cost reporting period; or

(B) For a base year that consists of the provider's cost reporting period that began on or after October 1, 1983 but before October 1, 1984. For providers whose cost reporting periods began during the months of October 1983 through June 1984, the provider's net cost of its program is adjusted by an updating factor. The factor is based on the increase in the overall rate of inflation, according to the Consumer Price Index for All Urban Consumers, that occurred during the provider's base year.

(ii) For providers that did not have approved educational activities as of the first day of the cost reporting period that would otherwise be its base year defined in paragraph (a)(2)(i)(B) of this section, and that initiated such activities after the first month of that cost reporting period, but prior to July 1, 1985, we will establish a base period for applying the limit described in this section. The base period will include allowable costs the provider incurred for approved educational activities prior to July 1, 1985, adjusted in order to be reasonably comparable to the base years of other providers.

(3) *Apportionment.* Once the net cost is determined under this section, it is subject to apportionment for Medicare utilization as described in § 405.403.

(b) *Definition—Approved educational activities.* Approved educational activities means formally organized or planned programs of study usually engaged in by providers in order to enhance the quality of patient care in an institution. These activities must be licensed if required by State law. If licensing is not required, the institution must receive approval from the recognized national professional organization for the particular activity.

(c) *Educational activities.* Many providers engage in educational activities including training programs for nurses, medical students, interns and residents, and various paramedical specialties. These programs contribute to the quality of patient care within an institution and are necessary to meet the community's needs for medical and paramedical personnel. It is recognized that the costs of such educational activities should be borne by the community. However, many communities have not assumed responsibility for financing these programs and it is necessary that support be provided by those purchasing health care. Until communities undertake to bear these costs, the program will participate appropriately in the support of these activities. Although the intent of the program is to share in the support of educational activities customarily or traditionally carried on by providers in conjunction with their operations, it is not intended that this program should participate in increased costs resulting from redistribution of costs from educational institutions or units to patient care institutions or units.

(d) *Activities not within the scope of this principle.* The costs of the following activities are not within the scope of this principle but are recognized as normal operating costs and are reimbursed in accordance with applicable principles—

(1) Orientation and on-the-job training;

(2) Part-time education for bona fide employees at properly accredited academic or technical institutions (including other providers) devoted to undergraduate or graduate work;

(3) Costs, including associated travel expense, or sending employees to educational seminars and workshops that increase the quality of medical care or operating efficiency of the provider;

(4) Maintenance of a medical library;

(5) Training of a patient or patient's family in the use of medical appliances;

(6) Clinical training of students not enrolled in an approved education program operated by the provider; and

(7) Other activities that do not involve the actual operation of an approved education program including the costs of interns and residents in anesthesiology who are are employed to replace anesthetists.

(e) *Approved programs.* In addition to approved medical, osteopathic, dental, and podiatry internships and residency programs[1], recognized professional and paramedical educational and training programs now being conducted by provider institutions, and their approving bodies, include the following:

Program	Approving bodies
(1) Cytotechnology	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Medical Technology, American Society of Clinical Pathologists.
(2) Dietetic internships	The American Dietetic Association.
(3) Hospital administration residencies	Members of the Association of University Programs in Hospital Administration.
(4) Inhalation therapy	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Inhalation Therapy.
(5) Medical records	Council on Medical Education of the American Medical Association in collaboration with the Committee on Education and Registration of the American Association of Medical Record Librarians.
(6) Medical technology	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Medical Technology, American Society of Clinical Pathologists.
(7) Nurse anesthetists	The American Association of Nurse Anesthetists.
(8) Professional nursing	Approved by the respective State approving authorities. Reported for the United States by the National League for Nursing.
(9) Practical nursing	Approved by the respective State approving authorities. Reported for the United States by the National League for Nursing.
(10) Occupational therapy	Council on Medical Education of the American Medical Association in collaboration with the Council on Education of the American Occupational Therapy Association.
(11) Pharmacy residencies	American Society of Hospital Pharmacists.
(12) Physical therapy	Council on Medical Education of the American Medical Association in collaboration with the American Physical Therapy Association.
(13) X-ray technology	Council on Medical Education of the American Medical Association in collaboration with the American College of Radiology.

(f) *Other educational programs.* There may also be other educational programs not included in the foregoing in which a provider institution is engaged. Appropriate consideration will be given by the intermediary and HCFA to the costs incurred for those activities that come within the purview of the principle when determining the allowable costs for apportionment under the Medicare program.

(g) *Calculating net cost.* Net costs of approved educational activities are determined by deducting, from a provider's total costs of these activities, revenues it receives from tuition. For this purpose, a provider's total costs include trainee stipends, compensation of teachers, and other direct and indirect costs of the activities as determined under the Medicare cost-finding principles in § 413.24.

§ 413.90 Research costs.

(a) *Principle.* Costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs.

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[1] See § 409.15 of this chapter for a listing of such approved programs. For purposes of determination of educational costs in cost reporting periods beginning prior to January 1973, podiatry internships and residency programs approved by the Council on Podiatry Education of the American Podiatry Association were eligible for approval under paragraph (f) of this section.

(b) *Application.* (1) There are numerous sources of financing for health-related research activities. Funds for this purpose are provided under many Federal programs and by other tax-supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research. Funds available from such sources are generally ample to meet basic medical and hospital research needs. A further consideration is that quality review should be assured as a condition of governmental support for research. Provisions for such review would introduce special difficulties in the Medicare programs.

(2) If research is conducted in conjunction with, and as a part of, the care of patients, the costs of usual patient care are allowable to the extent that such costs are not met by funds provided for the research. Under this principle, however, studies, analyses, surveys, and related activities to serve the provider's administrative and program needs, are not excluded as allowable costs in the determination of reimbursement under Medicare.

§ 413.94 Value of services of nonpaid workers.

(a) *Principle.* The value of services in positions customarily held by full-time employees performed on a regular, scheduled basis by individuals as nonpaid members of organizations under arrangements between such organizations and a provider for the performance of such services without direct remuneration from the provider to such individuals is allowable as an operating expense for the determination of allowable cost subject to the limitation contained in paragraph (b) of this section. The amounts allowed are not to exceed those paid others for similar work. Such amounts must be identifiable in the records of the institutions as a legal obligation for operating expenses.

(b) *Limitations: Services of nonpaid workers.* The services must be performed on a regular, scheduled basis in positions customarily held by full-time employees and necessary to enable the provider to carry out the functions of normal patient care and operation of the institution. The value of services of a type for which providers generally do not remunerate individuals performing such services is not allowable as a reimbursable cost under the Medicare program. For example, donated services of individuals in distributing books and magazines to patients, or in serving in a provider canteen or cafeteria or in a provider gift shop, would not be reimbursable.

(c) *Application.* The following illustrates how a provider would determine an amount to be allowed under this principle: The prevailing salary for a lay nurse working in Hospital A is $5,000 for the year. The lay nurse receives no maintenance or special perquisites. A sister working as a nurse engaged in the same activities in the same hospital receives maintenance and special perquisites which cost the hospital $2,000 and are included in the hospital's allowable operating costs. The hospital would then include in its records an additional $3,000 to bring the value of the services rendered to $5,000. The amount of $3,000 would be allowable if the provider assumes obligation for the expense under a written agreement with the sisterhood or other religious order covering payment by the provider for the services.

§ 413.98 Purchase discounts and allowances, and refunds of expenses.

(a) *Principle.* Discounts and allowances received on purchases of goods or services are reductions of the costs to which they relate. Similarly, refunds of previous expense payments are reductions of the related expense.

(b) *Definitions*—(1) *Discounts.* Discounts, in general, are reductions granted for the settlement of debts.

(2) *Allowances.* Allowances are deductions granted for damage, delay, shortage, imperfection, or other causes, excluding discounts and returns.

(3) *Refunds.* Refunds are amounts paid back or a credit allowed on account of an overcollection.

(c) *Normal accounting treatment—Reduction of costs.* All discounts, allowances, and refunds of expenses are reductions in the cost of goods or services purchased and are not income. If they are received in the same accounting period in which the purchases were made or expenses were incurred, they will reduce the purchases or expenses of that period. However, if they are received in a later accounting period, they will reduce the comparable purchases or expenses in the period in which they are received.

(d) *Application.* (1) Purchase discounts have been classified as cash, trade, or quantity discounts. Cash discounts are reductions granted for the settlement of debts before they are due. Trade discounts are reductions from list prices granted to a class of customers before consideration of credit terms. Quantity discounts are reductions from list prices granted because of the size of individual or aggregate purchase transactions. Whatever the classification of purchase discounts, like treatment in reducing allowable costs is required. In the past, purchase discounts were considered as financial management income. However, modern accounting theory holds that income is not derived from a purchase but rather from a sale or an exchange and that purchase discounts are reductions in the cost of whatever was purchased. The true cost of the goods or services is the net amount actually paid for them. Treating purchase discounts as income would result in an overstatement of costs to the extent of the discount.

(2) As with discounts, allowances, and rebates received from purchases of goods or services, refunds of previous expense payments are clearly reductions in costs and must be reflected in the determination of allowable costs. This treatment is equitable and is in accord with that generally followed by other governmental programs and third-party payment organizations paying on the basis of cost.

§ 413.102 Compensation of owners.

(a) *Principle.* A reasonable allowance of compensation for services of owners is an allowable cost provided that the services are actually performed in a necessary function.

(b) *Definitions*—(1) *Compensation.* Compensation means the total benefit received by the owner for the services he furnishes to the institution. It includes the following items:

(i) Salary amounts paid for managerial, administrative, professional, and other services.

(ii) Amounts paid by the institution for the personal benefit of the proprietor.

(iii) The cost of assets and services that the proprietor receives from the institution.

(iv) Deferred compensation.

(2) *Reasonableness.* Reasonableness requires that the compensation allowance—

(i) Be such an amount as would ordinarily be paid for comparable services by comparable institutions; and

(ii) Depend upon the facts and circumstances of each case.

(3) *Necessary.* Necessary requires that the function be—

(i) Such that had the owner not furnished the services, the institution would have had to employ another person to perform the services; and

(ii) Pertinent to the operation and sound conduct of the institution.

(c) *Application.* (1) Owners of provider organizations often furnish services as managers, administrators, or in other capacities. In such cases, it is equitable that reasonable compensation for the services furnished to be an allowable cost. To do otherwise would disadvantage such owners in comparison with corporate providers or providers employing persons to perform similar services.

(2) Ordinarily, compensation paid to proprietors is a distribution of profits. However, if a proprietor furnishes necessary services for the institution, the institution is in effect employing his services, and a reasonable compensation for these services is an allowable cost. In corporate providers, the salaries of owners who are also employees are subject to the same requirements of reasonableness. If the services are furnished on less than a full-time basis, the allowable compensation should reflect an amount proportionate to a full-time basis. Reasonableness of compensation may be determined by reference to, or in comparison with, compensation paid for comparable services and responsibilities in comparable institutions; or it may be

determined by other appropriate means.

§ 413.106 Reasonable cost of physical and other therapy services furnished under arrangements.

(a) *Principle.* The reasonable cost of the services of physical, occupational, speech, and other therapists, and services of other health specialists (other than physicians), furnished under arrangements (as defined in section 1861(w) of the Act) with a provider of services, a clinic, a rehabilitation agency or a public health agency, may not exceed an amount equivalent to the prevailing salary and additional costs that would reasonably have been incurred by the provider or other organization had such services been performed by such person in an employment relationship, plus the cost of other reasonable expenses incurred by such person in furnishing services under such an arrangement. However, if the services of a therapist are required on a limited part-time basis, or to perform intermittent services, payment may be made on the basis of a reasonable rate per unit of service, even though this rate may be greater per unit of time than salary-related amounts, if the greater payment is, in the aggregate, less than the amount that would have been paid had a therapist been employed on a full-time or regular part-time salaried basis. Pursuant to section 17(a) of Pub. L. 93-233 (87 Stat. 967), the provisions of this section are effective for cost reporting periods beginning after March 1975.

(b) *Definitions*—(1) *Prevailing salary.* The prevailing salary is the hourly salary rate based on the 75th percentile of salary ranges paid by providers in the geographical area, by type of therapy, to therapists working full time in an employment relationship.

(2) *Fringe benefit and expense factor.* The standard fringe benefit and expense factor is an amount that takes account of fringe benefits, such as vacation pay, insurance premiums, pension payments, allowances for job-related training, meals, etc., generally received by an employee therapist, as well as expenses, such as maintaining an office, appropriate insurance, etc., an individual not working as an employee might incur in furnishing services under arrangements.

(3) *Adjusted hourly salary equivalency amount.* The adjusted hourly salary equivalency amount is the prevailing hourly salary rate plus the standard fringe benefit and expense factor. This amount is determined on a periodic basis for appropriate geographical areas.

(4) *Travel allowance.* A standard travel allowance is an amount that is recognized, in addition to the adjusted hourly salary equivalency amount.

(5) *Limited part-time or intermittent services.* Therapy services are considered to be on a limited part-time or intermittent basis if the provider or other organization furnishing the services under arrangements requires the services of a therapist or therapists on an average of less than 15 hours per week. This determination is made by dividing the total hours of services furnished during the cost reporting period by the number of weeks in which the services were furnished in the cost reporting period regardless of the number of days in each week in which services were performed.

(6) *Guidelines.* Guidelines are the amounts published by HCFA reflecting the application of paragraphs (b)(1) through (4) of this section to an individual therapy service and a geographical area. Other statistically valid data may be used to establish guidelines for a geographical area, provided that the study designs, questionnaires and instructions, as well as the resultant survey data for determining the guidelines are submitted to and approved in advance by HCFA. Such data must be arrayed so as to permit the determination of the 75th percentile of the range of salaries paid to full-time employee therapists.

(7) *Administrative responsibility.* Administrative responsibility is the performance of those duties that normally fall within the purview of a department head or other supervisor. This term does not apply to directing aides or other assistants in furnishing direct patient care.

(c) *Application.* (1) Under this provision, HCFA will establish criteria for use in determining the reasonable cost of physical, occupational, speech, and other therapy services and the services of other health specialists (other than physicians) furnished by individuals under arrangements with a provider of services, a clinic, a rehabilitation agency, or public health agency. It is recognized that providers have a wide variety of arrangements with such individuals. These individuals may be independent practitioners or employees of organizations furnishing various health care specialists. This provision does not require change in the substance of these arrangements.

(2) If therapy services are performed under arrangements at a provider site on a full-time or regular part-time basis, the reasonable cost of such services may not exceed the amount determined by taking into account the total number of hours of services furnished by the therapist, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished and a standard travel allowance.

(3) If therapy services are performed under arrangements on a limited part-time or intermittent basis at the provider site, the reasonable cost of such services is evaluated on a reasonable rate per unit of service basis, except that payment for these services, in the aggregate, during the cost reporting period, may not exceed the amount that would be determined to be reasonable under paragraph (c)(2) of this section, had a therapist furnished the provider or other organization furnishing the services under arrangements 15 hours of service per week on a regular part-time basis for the weeks in which services were furnished by the non-employee therapist.

(4) If an HHA furnishes services under arrangements at the patient's residence or in other situations in which therapy services are not performed at the provider's site, the reasonable cost of such services is evaluated as follows:

(i) *Time records available.* If time records of HHA visits are maintained by the provider, the reasonable cost of such services is evaluated on a unit-of-time basis, by taking into account the total number of hours of service furnished by the therapist, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished, and a standard travel allowance for each visit. However, if the travel time of the therapist is accurately recorded by the therapist, and approved and maintained by the provider, the reasonable cost of such services may be evaluated, at the option of the provider, by taking into account the total number of hours of service furnished by the therapist, including travel time, and the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished. This option does not apply to services furnished by HHAs under arrangements with providers other than HHAs.

(ii) *No time records available.* If time records are unavailable or found to be inaccurate, each HHA visit is considered the equivalent of one hour of service. In such cases, the reasonable cost of such services is determined by taking into account the number of visits made by the therapist under arrangements with such agency, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished, and a standard travel allowance.

(iii) *Limited part-time or intermittent services.* If under paragraph (c)(4) (i) or (ii) of this section, the provider required therapy services on an average of less than 15 hours per week, the services are considered limited part-time or intermittent services, and the reasonable cost of such services is evaluated on a reasonable rate per unit of service basis as described in paragraph (c)(3) of this section.

(5) These provisions are applicable to individual therapy services or disciplines by means of separate guidelines by geographical area and apply to costs incurred after issuance of the guidelines but no earlier than the beginning of the provider's cost reporting period described in paragraph (a) of this section. Until a guideline is issued for a specific therapy or discipline, costs are evaluated so that such costs do not exceed what a prudent

and cost-conscious buyer would pay for the given service.

(d) *Notice of guidelines to be imposed.* Prior to the beginning of a period to which a guideline will be applied, a notice will be published in the FEDERAL REGISTER establishing the guideline amounts to be applied to each geographical area by type of therapy.

(e) *Additional allowances.* (1) If a therapist supervises other therapists or has administrative responsibility for operating a provider's therapy department, a reasonable allowance may be added to the adjusted hourly salary equivalency amount by the intermediary based on its knowledge of the differential between therapy supervisors' and therapists' salaries in similar provider settings in the area.

(2) If a therapist performing services under arrangements furnishes equipment and supplies used in furnishing therapy services, the guideline amount may be supplemented by the cost of the equipment and supplies, provided the cost does not exceed the amount the provider, as a prudent and cost-conscious buyer, would have been able to include as allowable cost.

(f) *Exceptions.* The following exceptions may be granted but only upon the provider's demonstration that the conditions indicated are present:

(1) *Exception because of binding contract.* A provider will be excepted from the provisions of this section if it has a binding contract in writing with a therapist or contracting organization entered into prior to the date guidelines are published. Before the exception may be granted, however, the provider must submit the contract to its intermediary for a determination under this paragraph, subject to review and approval by the Regional Office. Such an exception may be granted for the contract period, but not longer than one year from the date initial guidelines for the particular therapy are published.

(2) *Exception because of unique circumstances or special labor market conditions.* An exception may be granted under this section by the intermediary if a provider demonstrates that the costs for therapy services established by the guideline amounts are inappropriate to a particular provider because of some unique circumstances or special labor market conditions in the area.

(3) *Exception for services furnished by risk-basis HMO providers.* For special rules concerning services furnished to an HMO's enrollees who are Medicare beneficiaries by a provider owned or operated by a risk-basis HMO (see § 417.201(b) of this chapter) or related to a risk-basis HMO by common ownership or control (see § 417.250(c) of this chapter).

(4) *Exception for inpatient hospital services.* Effective with cost reporting periods beginning on or after October 1, 1983, the costs of therapy services furnished under arrangements to a hospital inpatient are excepted from the guidelines issued under this section if such costs are subject to the provisions of § 413.40 or Part 412 of this chapter. The intermediary will grant the exception without request from the provider.

(g) *Appeals.* A request by a provider for a hearing on the determination of an intermediary concerning the therapy costs determined to be allowable based on the provisions of this section, including a determination with respect to an exception under paragraph (f) of this section, is made to the intermediary only after submission of its cost report and receipt of the notice of amount of program reimbursement reflecting such determination, in accordance with the provisions of Subpart R of Part 405 of this chapter.

§ 413.114 Reasonable cost of extended care services furnished by a swing-bed hospital.

(a) *Purpose and basis.* This section implements section 1883 of the Act, which provides for reimbursement for extended care services furnished by small, rural hospitals having a swing-bed approval. Payments to such hospitals for extended care services furnished in general routine inpatient beds are based on the reasonable cost of extended care services, in accordance with paragraph (c) of this section.

(b) *Definition.* A swing-bed hospital is a hospital participating in Medicare that has an approval from HCFA to provide extended care services as defined in § 409.20 of this chapter, and meets the requirements specified in § 482.66 of this chapter.

(c) *Principle.* The reasonable cost of extended care services furnished by a swing-bed hospital is determined as follows:

(1) If a hospital is located in a State participating in Medicaid, the reasonable cost of the routine services is based on the average Statewide rate per patient day paid under the State Medicaid plan for routine services furnished by SNFs in that State during the previous calendar year. The Statewide average rate will be computed either by—

(i) The State and furnished to HCFA; or

(ii) HCFA directly based on the best available data.

(2) If a hospital is located in a State that is not participating in Medicaid, the reasonable cost of the routine services is based on the average reasonable cost per patient day under Medicare for routine services furnished by SNFs in that State during the previous calendar year. HCFA will determine the average reasonable cost using Medicare cost reports, with adjustments to account for cost reporting periods not covering the calendar year preceding the year for which the rate is to be effective.

(3) The reasonable cost of ancillary services furnished as extended care services is determined in the same manner as the reasonable cost of other ancillary services furnished by the hospital in accordance with § 413.55(a)(1).

§ 413.118 Payment for facility services related to covered ASC surgical procedures performed in hospitals on an outpatient basis.

(a) *Basis and scope.* This section implements section 1833(i)(3) of the Act and establishes the method for determining Medicare payments for services related to covered ambulatory surgical center (ASC) procedures performed in a hospital on an outpatient basis. It does not apply to services furnished by an ASC operated by a hospital that has an agreement with HCFA to be paid in accordance with § 416.30 of this chapter. (For regulations governing ASCs see Part 416 of this chapter.)

(b) *Definitions.* For purposes of this section—

"Facility services" are those items and services, as specified in § 416.61 of this chapter, that are furnished by a hospital on an outpatient basis in connection with covered ASC surgical procedures, as described in § 416.65 of this chapter.

"Standard overhead amount" means an amount equal to the prospectively determined payment rate that would be paid for the procedure if it had been furnished by an ASC in the same geographic area.

(c) *Payment principle.* The aggregate amount of payments for facility services, furnished in a hospital on an outpatient basis, that are related to covered ASC surgical procedures (covered under § 416.65 of this chapter) is equal to the lesser of—

(1) The hospital's reasonable cost or customary charges, as determined in accordance with § 413.13, reduced by deductibles and coinsurance; or

(2) The blended payment amount as described in paragraph (d) of this section, which is based on hospital-specific cost and charge data and rates paid to free-standing ASCs.

(d) *Blended payment amount.* (1) For cost reporting periods beginning on or after October 1, 1987 but before October 1, 1988, the blended payment amount is equal to the sum of—

(i) 75 percent of the hospital-specific amount (the lesser of the hospital's reasonble cost or customary charges, reduced by deductibles and coinsurance); and

(ii) 25 percent of the ASC payment amount (that is, 80 percent of the result obtained by subtracting the deductibles from the sum of the standard overhead amounts.)

(2) For cost reporting periods beginning on or after October 1, 1988, the blended payment amount is equal to 50 percent of the hospital-specific amount and 50 percent of the ASC payment amount.

(e) *Aggregation of cost, charges, and the blended amount.* For purposes of determining the correct payment amount under paragraphs (c) and (d) of this section, all reasonable costs and customary charges attributable to facility services furnished during a cost reporting period are aggregated and treated separately from the reasonable costs and customary charges attributable to all other services furnished in the hospital.

[52 FR 36773, Oct. 1, 1987; 52 FR 37715, Oct. 8, 1987]

Subpart G—Capital-Related Costs

§ 413.130 Introduction to capital-related costs.

(a) *General rule.* Capital-related costs and an allowance for return on equity are limited to the following:

(1) Net depreciation expense as determined under §§ 413.134, 413.144, and 413.149, adjusted by gains and losses realized from the disposal of depreciable assets under § 413.134(f).

(2) Taxes on land or depreciable assets used for patient care.

(3) Leases and rentals, including license and royalty fees, for the use of depreciable assets, as described in paragraph (b) of this section.

(4) The costs of betterments and improvements as described in paragraph (c) of this section.

(5) The costs of minor equipment that are capitalized, rather than expensed, as described in paragraph (d) of this section.

(6) Insurance expense on depreciable assets, as described in paragraph (e) of this section.

(7) Interest expense as determined under § 413.153, subject to the qualifications of paragraph (f) of this section.

(8) For certain proprietary providers, return on equity capital, as determined under § 413.157.

(9) The capital-related costs of related organizations (as described in § 413.17), as determined in accordance with paragraph (g) of this section.

(b) *Leases and rentals.* (1) Subject to the qualifications of paragraphs (b)(2) and (4) of this section, leases and rentals, including licenses and royalty fees, are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright. The terms "leases" and "rentals of assets" signify that a provider has possession, use, and enjoyment of the assets.

(2) A provider must include incurred rental charges in its capital-related costs, as specified in a sale and leaseback agreement with a nonrelated purchaser (including shared service organizations not related within the meaning of § 413.17) involving plant facilities or equipment, only if the following conditions are met:

(i) The rental charges are reasonable based on—

(A) Consideration of rental charges of comparable facilities and market conditions in the area;

(B) The type, expected life, condition, and value of the facilities or equipment rented; and

(C) Other provisions of the rental agreements.

(ii) Adequate alternate facilities or equipment that would serve the purpose are not or were not available at lower cost.

(iii) The leasing was based on economic and technical considerations.

(3) If the conditions of paragraph (b)(2) of this section are not met, the amount a provider may include in its capital-related costs as rental or lease expense under a sale and leaseback agreement may not exceed the amount that the provider would have included in its capital-related costs had the provider retained legal title to the facilities or equipment, such as interest on mortgage, taxes, depreciation, and insurance costs.

(4) A lease that meets the following conditions generally establishes a virtual purchase:

(i) The rental charge exceeds rental charges of comparable facilities or equipment in the area.

(ii) The term of the lease is less than the useful life of the facilities or equipment.

(iii) The provider has the option to renew the lease at a significantly reduced rental, or the provider has the right to purchase the facilities or equipment at a price that appears to be significantly less than what the fair market value of the facilities or equipment would be at the time acquisition by the provider is permitted.

(5)(i) If a lease is a virtual purchase under paragraph (b)(4) of this section, the rental charge is includable in capital-related costs only to the extent that it does not exceed the amount that the provider would have included in capital-related costs if it had legal title to the asset (the cost of ownership), such as straight-line depreciation, insurance, and interest. A provider may not include in its capital-related costs accelerated depreciation in this situation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as capital-related costs is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner, instead of being purchased, the deferred charge may be included in capital-related costs in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be included in the capital-related costs to the extent of increasing the reduced rental to a fair rental value.

(c) *Betterments and improvements.* (1) Betterments and improvements are changes which extend the estimated useful life of an asset at least two years beyond its original estimated useful life, or increase the productivity of an asset significantly over its original productivity.

(2) A provider must capitalize and prorate the costs of betterments and improvements over the remaining estimated useful life of the asset, as modified by the betterment or improvement.

(d) *Minor equipment.* A provider must include in its capital-related costs the costs of minor equipment that are capitalized rather than charged off to expense if—

(1) The net book value of minor equipment at the time the provider enters the program is prorated over three years (that is, one-third of the net book value is written off each year), and new purchases are also prorated over a 3-year period; or

(2) The cost of minor equipment is prorated over their actual useful lives.

(e) *Insurance.* (1) A provider must include in its capital-related costs the costs of insurance on depreciable assets used for patient care or insurance that provides for the payment of capital-related costs during business interruption.

(2) If an insurance policy also provides protection for other than the replacement of depreciable assets or to pay capital-related costs in the case of business interruption insurance, only that portion of the premium related to the replacement of depreciable assets or to pay capital-related costs in the case of business interruption insurance is includable in capital-related costs.

(f) *Interest expense.* (1) A provider must include in its capital-related costs interest expense, as described in § 413.153, if such expense is incurred in—

(i) Acquiring land or depreciable assets (either through purchase or lease) used for patient care; or

(ii) Refinancing existing debt, if the original purpose of the refinanced debt was to acquire land or depreciable assets used for patient care.

(2) If investment income offset is required under § 413.153(b)(2)(iii), only that portion of investment income that bears the same relationship to total investment income, as the portion of capital-related interest expense bears to total interest expense, is offset against capital-related costs.

(g) *Costs of supplying organizations*—(1) *Supplying organizations related to the provider.* (i) If the supplying organization is related to the provider within the meaning of § 413.17, except as provided in paragraph (g)(1)(ii) of this section, a provider's capital-related costs include the capital-related costs of the supplying organization.

(ii) If the costs of the services, facilities or supplies being furnished exceed the open market price, or if the provisions of § 413.17(d) apply, no part of the cost to the provider of the services, facilities, or supplies are considered capital-related costs, unless the services, facilities, or supplies would otherwise be considered capital-related.

(2) *Supplying organizations not related to the provider.* If the supplying organization is not related to the provider within the meaning of § 413.17, no part of the charge to the provider may be considered a capital-related cost (unless the services, facilities, or supplies are capital-related in nature) unless—

(i) The capital-related equipmente is leased or rented (as described in paragraph (b) of this section) by the provider;

(ii) The capital-related equipment is located on the provider's premises, or is located offsite and is on real estate owned, leased or rented by the provider; and

(iii) The capital-related portion of the charge is separately specified in the charge to the provider.

(h) *Costs excluded from capital-related costs.* The following costs are not capital-related costs. To the extent that they are allowable, they must be included in determining each provider's operating costs:

(1) Costs incurred for the repair or maintenance of equipment or facilities.

(2) Amounts included in rentals or lease payments for repair or maintenance agreements.

(3) Interest expense incurred to borrow working capital (for operating expenses).

(4) General liability insurance or any other form of insurance to provide protection other than for the replacement of depreciable assets or to pay capital-related costs in the case of business interruption.

(5) Taxes other than those assessed on the basis of some valuation of land or depreciable assets used for patient care. (Taxes not related to patient care, such as income taxes, are not allowable, and are therefore not included among either capital-related or operating costs.)

(6) The costs of minor equipment that are charged off to expense rather than capitalized as described in paragraph (d) of this section.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987]

§ 413.134 Depreciation: Allowance for depreciation based on asset costs.

(a) *Principle.* An appropriate allowance for depreciation on buildings and equipment used in the provision of patient care is an allowable cost. The depreciation must be—

(1) Identifiable and recorded in the provider's accounting records;

(2) Based on the historical cost of the asset or fair market value at the time of donation in the case of donated assets; and

(3) Prorated over the estimated useful life of the asset using—

(i) The straight-line method; or

(ii) Accelerated depreciation under a declining balance method (not to exceed double the straight-line rate) or the sum-of-the-years' digits method in the following situations:

(A) Depreciable assets for which accelerated depreciation was used for Medicare purposes before August 1, 1970, including those assets for which a timely request to change from straight-line depreciation to accelerated depreciation was received by an intermediary before August 1, 1970;

(B) Depreciable assets acquired before August 1, 1970, if no election to use straight-line or accelerated depreciation was in effect on August 1, 1970, and the provider was participating in the program on August 1, 1970;

(C) Depreciable assets of a provider if construction of such depreciable asset began before February 5, 1970, and the provider was participating in the program on February 5, 1970; or

(D) Depreciable assets of a provider if a valid written contract was entered into by a provider participating in the program before February 5, 1970, for construction, acquisition, or for the permanent financing thereof, and such contract was binding on a provider on February 5, 1970, and at all times thereafter; or

(iii) A declining balance method, not to exceed 150 percent of the straight-line rate, for a depreciable asset acquired after July 31, 1970; however, this declining balance method may be used only if the cash flow from depreciation on the total assets of the institution during the reporting period, including straight-line depreciation on the assets in question, is insufficient (assuming funding of available capital not required currently for amortization and assuming reasonable interest income on such funds) to supply the funds required to meet the reasonable principal amortization schedules on the capital debts related to the provider's total depreciable assets. For each depreciable asset for which a provider requests authorization to use a declining balance method for Medicare reimbursement purposes, but not to exceed 150 percent of the straight-line rate, the provider must demonstrate to the intermediary's satisfaction that the required cash flow need exists. For each depreciable asset in which a provider justifies the use of accelerated depreciation, the intermediary must give written approval for the use of a depreciation method other than straight-line before basing any interim payment on this accelerated depreciation or making its reasonable cost determination which includes an allowance for such depreciation.

(b) *Definitions*—(1) *Historical costs.* Historical cost is the cost incurred by the present owner in acquiring the asset. For depreciable assets acquired after July 31, 1970, the historical cost may not exceed the lower of current reproduction cost adjusted for straight-line depreciation over the life of the asset to the time of the purchase, or fair market value at the time of the purchase.

(2) *Fair market value.* Fair market value is the price that the asset would bring by bona fide bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.

(3) *The straight-line method.* Under the straight-line method of depreciation, the cost or other basis (for example, fair market value in the case of donated assets) of the asset, less its estimated salvage value, if any, is determined first. Then this amount is distributed in equal amounts over the period of the estimated useful life of the asset.

(4) *Declining balance method.* Under the declining balance method, the annual depreciation allowance is computed by multiplying the undepreciated cost of the asset each year by a uniform rate up to double the straight-line rate or 150 percent, as the case may be (see paragraph (a)(3) of this section for limitations on use of accelerated methods of depreciation).

(5) *Sum-of-the-years' digits method.* Under the sum-of-the-years' digits method, the annual depreciation allowance is computed by multiplying the depreciable cost basis (cost less salvage value) by a constantly decreasing fraction. The numerator of the fraction is represented by the remaining years of useful life of the asset at the beginning of each year, and the denominator is always represented by the sum of the years' digits of useful life at the time of acquisition.

(6) *Current reproduction cost.* Current reproduction cost is the cost at current prices, in a particular locality or market area, of reproducing an item of property or a group of assets. Where depreciable assets are concerned, this means the reasonable cost to have built, reproduce in kind, or, in the case of equipment or similar assets, to purchase in the competitive market.

(7) *Useful life.* The estimated useful life of a depreciable asset is its normal operating or service life to the provider, subject to the provisions in paragraph (b)(7)(i) of this section. Factors to be considered in determining useful life include normal wear and tear; obsolescence due to normal economic and technological changes; climatic and other local conditions; and the provider's policy for repairs and replacement.

(i) *Initial selection of useful life.* In selecting a proper useful life for computing depreciation under the Medicare program, providers must use the useful life guidelines published by HCFA. If HCFA has not published applicable useful life guidelines, providers must use—

(A) The edition of the American Hospital Association useful life guidelines, as specified in HCFA Medicare program manuals; or

(B) A different useful life specifically requested by the provider and approved by the intermediary. A different useful life may be approved by the intermediary if the provider's request is properly supported by acceptable factors that affect the determination of useful life. However, such factors as an expected early sale, retirement, demolition or abandonment of an asset, or termination of the provider from the Medicare program may not be used.

(ii) *Application of guidelines.* The provisions concerning the selection of useful life guidelines described in paragraph (b)(7)(i) of this section apply to assets acquired on or after January 1, 1981. For assets acquired before January 1, 1981, providers must use the useful life guidelines published by the American Hospital Association in its 1973 edition of *Chart of Accounts for Hospitals,* or those published by the Internal Revenue Service, or those approved for use by intermediaries as provided in paragraph (b)(7)(i)(B) of this section.

(iii) *Changing useful life.* A change in the estimated useful life may be made if clear and convincing evidence justifies a redetermination of the useful life used by the provider. Such a change must be approved by the intermediary in writing, and the factors cited in paragraphs (b)(7) and (b)(7)(i) of this section are applicable in making such redeterminations of useful life. If the request is approved, the change is effective with the reporting period immediately following the period in which the provider's request is submitted for approval.

(c) *Recording of depreciation.* Appropriate recording of depreciation includes the identification of the depreciable assets in use, the assets' historical costs, the assets' dates of acquisition, the method of depreciation, estimated useful lives, and the assets' accumulated depreciation.

(d) *Depreciation methods*—(1) *General.* Proration of the cost of an asset over its useful life is allowed on the straight-line method, or, where permitted under § 413.134(a)(3), the declining balance or the sum-of-the-years' digits methods. One method may be used on a single asset or group of assets and another method on others. In applying the declining balance or sum-of-the-years' digits method to an asset that is not new, the undepreciated cost of the asset is treated as the cost of a new asset in computing depreciation.

(2) *Change in method.* Prior to August 1, 1970, a provider may change from the straight-line method to an accelerated method or vice versa, upon advance approval from the intermediary on a prospective basis with the request being made before the end of the first month of the prospective reporting period. Only one such change with respect to a particular asset may be made by a provider. Effective with August 1, 1970, a provider may only change from an accelerated method or optional method (see § 413.139) to the straight-line method. Such a change may be made without intermediary approval and the basis for depreciation is the undepreciated cost reduced by the salvage value. Thereafter, once straight-line depreciation is selected for a particular asset, an accelerated method may not be established for that asset.

(3) *Recovery of accelerated depreciation*—(i) *General.* If a provider who has used an accelerated method of depreciation for any of its assets terminates participation in the program, or if the Medicare proportion of its allowable costs decreases so that cumulatively substantially more depreciation was paid than would have been paid using the straight-line method of depreciation, the excess of reimbursable cost determined by using accelerated depreciation methods and paid under the program over the reimbursable cost that would have been determined and paid under the program by using the straight-line method of depreciation, will be recovered as an offset to current reimbursement due or, if the provider has terminated participation in the program, as an overpayment. In this determination of excess payment, recognition will be given to the effects the adjustment to straight-line depreciation would have on the return on

equity capital and on the allowance in lieu of specific recognition of other costs in the respective years.

(ii) *Transaction between related organizations*—(A) *General.* If the termination of the provider agreement is due to a change in provider ownership, as defined in § 489.18 of this chapter, resulting from a transaction between related organizations, as defined in § 413.17, and the criteria in paragraph (b) of this section are met, the excess of reimbursable cost, as determined in paragraph (d)(3)(i) of this section may not be recovered if there is a continuation of participation by the facility in the Medicare program.

(B) *Criteria.* The following criteria must be met if the recovery of excess reimbursable cost is not to be made:

(*1*) The termination of the provider agreement is due to a change in ownership of the provider resulting from a transaction between related organizations.

(*2*) The successor provider continues to participate in the Medicare program.

(*3*) Control and the extent of the financial interest of the owners of the provider before and after the termination remain the same; that is, the successor owners acquire the same percentage of control or financial investment as the transferors had.

(*4*) All assets and liabilities of the terminated provider are transferred to the related successor participating provider.

(C) *Effect of transaction.* In transactions meeting the criteria specified in paragraph (d)(3)(ii)(B) of this section, the provision concerning recovery of excess reimbursable cost (§ 413.134(d)(3)(i)) is not applied, and the transaction is treated as follows:

(*1*) The successor provider must record the historical cost and accumulated depreciation and the method of depreciation recognized under the Medicare program, and these are considered as incurred by the successor provider for Medicare purposes.

(*2*) The Medicare program's utilization of the terminated provider is considered as having been incurred by the successor provider for Medicare purposes.

(*3*) The equity capital of the terminated provider as of the closing of its final cost reporting period must be wholly contained in the equity capital of the successor provider as of the beginning of its first cost reporting period.

(e) *Funding of depreciation.* Although funding of depreciation is not required, it is strongly recommended that providers use this mechanism as a means of conserving funds for replacement of depreciable assets, and coordinate their planning of capital expenditures with areawide planning activities of community and State agencies. As an incentive for funding, investment income on funded depreciation will not be treated as a reduction of allowable interest expense.

(f) *Gains and losses on disposal of assets*—(1) *General.* Depreciable assets may be disposed of through sale, scrapping, trade-in, exchange, demolition, abandonment, condemnation, fire, theft, or other casualty. If disposal of a depreciable asset results in a gain or loss, an adjustment is necessary in the provider's allowable cost. The amount of a gain included in the determination of allowable cost is limited to the amount of depreciation previously included in Medicare allowable costs. The amount of a loss to be included is limited to the undepreciated basis of the asset permitted under the program. The treatment of the gain or loss depends upon the manner of disposition of the asset, as specified in paragraphs (f)(2) through (f)(6) of this section.

(2) *Bona fide sale or scrapping.* (i) Except as specified in paragraph (f)(3) of this section, gains and losses realized from the bona fide sale or scrapping of depreciable assets are included in the determination of allowable cost only if the sale or scrapping occurs while the provider is participating in Medicare. The extent to which such gains and losses are included is calculated by prorating the basis for depreciation of the asset in accordance with the proportion of the asset's useful life for which the provider participated in Medicare. For purposes of this paragraph (f)(2)(i), scrapping refers to the physical removal from the provider's premises of tangible personal

properties that are no longer useful for their intended purpose and are only salable for their scrap or junk value.

(ii) If the total amount of gains or losses realized from bona fide sales or scrapping does not exceed $5,000 within the cost reporting period or if the provider's cumulative utilization under the Medicare program is less than 5 percent, the net amount of gains or losses realized from sale or scrapping will be allowed as a depreciation adjustment in the period of disposal. For purposes of this paragraph (f)(2)(ii), the provider's cumulative Medicare utilization precentage is determined by comparing the cumulative total of the Medicare inpatient days for all reporting periods in which depreciation on the asset disposed of was claimed under the Medicare program to the cumulative total of inpatient days of the participating provider for the same reporting periods.

(iii) If the conditions specified in paragraph (f)(2)(ii) of this section are not met, the adjustment to reimbursable cost in the reporting period of asset disposition is calculated as follows:

(A) The total amount of gains or losses shall be allocated to all reporting periods under the Medicare program, based on the ratio of the depreciation allowed on the assets in each reporting period to the total depreciation allowed under the Medicare program.

(B) The results of this allocation are multiplied by the ratio of Medicare reimbursable cost to total allowable cost for each reporting period.

(C) The results of this multiplication are then added.

(iv) If a provider sells more than one asset for a lump sum sales price, the gain or loss on the sale of each depreciable asset must be determined by allocating the lump sum sales price among all the assets sold, in accordance with the fair market value of each asset as it was used by the provider at the time of sale. If the buyer and seller cannot agree on an allocation of the sales price, or if they do agree but there is insufficient documentation of the current fair market value of each asset, the intermediary for the selling provider will require an appraisal by an independent appraisal expert to establish the fair market value of each asset and will make an allocation of the sales price in accordance with the appraisal.

(3) *Sale within 1 year after termination.* Gains and losses realized from a bona fide sale of depreciable assets within 1 year immediately following the date on which the provider terminates participation in the Medicare program are also included in the determination of allowable cost, in accordance with the procedure specified in paragraph (f)(2) of this section. However, if several assets are sold for a lump sum sales price, the determination of fair market value must be based on the appraised value of the assets as they were last used by the provider while participating in the Medicare program.

(4) *Exchange or trade-in.* Gains or losses realized from the exchange or trade-in of depreciable assets are not included in the determination of allowable cost. When the disposition of an asset is by means of exchange or trade-in, the historical cost of the new asset is the sum of the undepreciated cost of the asset disposed of and the additional cash or other assets transferred or to be transferred to acquire the new asset. However, if the asset disposed of was acquired by the provider before its participation in the Medicare program and the sum of the undepreciated cost and the cash or other assets transferred or to be transferred exceed the list price or fair market value of the new asset, the historical cost of the new asset is limited to the lower of its list price or fair market value.

(5) *Demolition or abandonment.* (i) For purposes of this section, the term "abandonment" means the permanent retirement of an asset for any future purpose, not merely the provider's ceasing to use the asset for patient care purposes. To claim an abandonment under the Medicare program, the provider must have relinquished all rights, title, claim, and possession of the asset with the intention of never reclaiming it or resuming its ownership, possession, or enjoyment.

(ii) If losses resulting from the demolition or abandonment of depreciable assets do not exceed $5,000 within the cost-reporting period, the losses are to be allowed in the period of disposal.

(iii) If losses exceed $5,000 and, at the date of disposition, the demolished or abandoned assets are at least 80 percent depreciated as computed under the straight-line method, such losses are includable in the determination of allowable cost under the Medicare program in the period of disposal and the procedure provided in paragraph (f)(2)(iii) of this section must be used in determining the adjustment to reimbursable cost.

(iv) Losses in excess of $5,000 resulting from the demolition or abandonment of assets, which at the date of disposition are not 80 percent depreciated as computed under the straight-line method, must be capitalized as a deferred charge and amortized as follows:

(A) If the State Health Planning and Development Agency (SHPDA) designated under section 1521 of the Public Health Service Act approves the demolition or abandonment of a depreciable asset as being consistent with the health systems plan of the health service area in which the provider is located, the net loss realized shall be capitalized as a deferred charge and amortized over the remaining life of the demolished or abandoned asset, or at the rate of $5,000 per year, whichever is greater. If no SHPDA exists or if such agency is unable or unwilling to perform this function, the provider must submit a request for approval to the intermediary. The intermediary, after reviewing this request and before issuing the approval, will submit the request along with its recommendation to the appropriate Regional Office for its approval.

(B) If a provider fails to obtain approval as specified in paragraph (f)(5)(iv)(A) of this section, a loss is not allowable unless the demolished or abandoned asset is replaced. If the asset is replaced, the loss resulting from the unapproved demolition or abandonment must be capitalized as a deferred charge and amortized over the estimated useful life of the replacement asset or at the rate of $5,000 per year, whichever is greater.

(v) If a loss resulting from the demolition or abandonment is deferred and amortized and the provider terminates its participation in the Medicare program or ceases to use a replacement asset in the provision of patient care services, the unamortized deferred charge remaining at that time must not be included in determining allowable cost under the Medicare program.

(vi) Losses on demolition must include the demolition cost incurred by the provider for razing and removal of the asset, less any salvage value recovered by the provider. However, if a provider demolishes a depreciable asset for the purpose of preparing land for future sale, the net demolition cost incurred by the provider (razing and removal costs less salvage recovered) is considered a capital expenditure and added to the historical basis of the land.

(vii) If a provider purchases land on which there is a building, no depreciation will be allowed under the Medicare program unless the building is used in providing patient care. If the building is demolished, the entire purchase price and demolition cost shall be considered the historical cost of the land. If the building is used for patient care, but demolished within 5 years of purchase, the entire purchase price, less allowed depreciation, plus demolition cost will be considered the historical cost of the land.

(6) *Involuntary conversion.* (i) Losses resulting from the involuntary conversion of depreciable assets, such as condemnation, fire, theft, or other casualty, are generally included in the determination of allowable cost on a deferred basis if the asset is restored or replaced. However, losses resulting from a provider's imprudent management of its depreciable assets, such as the failure to obtain proper insurance coverage, are not included in the determination of allowable cost.

(ii) The net allowable loss from involuntary conversion must consist of the undepreciated cost of unrecovered book value of the asset, less amounts received from insurance proceeds gifts, and grants received from local, State, or Federal government, or any other source as a result of the involuntary conversion.

(iii) If the asset is replaced and the net allowable loss in any cost-reporting period does not exceed $5,000, the entire amount must be included in allowable cost in the period in which the loss is incurred. If the asset is replaced and the net allowable loss in any cost-reporting period exceeds $5,000, the loss must be capitalized as a deferred charge and amortized over the useful life of the replacement or restored asset. If a replaced or restored asset ceases to be used in the provision of patient care services or the provider terminates its participation in the Medicare program, the unamortized deferred charge remaining at that time will not be included in determining allowable cost under the Medicare program.

(iv) If the provider fails to replace or restore an involuntarily converted asset, the loss is not included in determining allowable cost. However, if the provider intends to replace or restore the asset but is unable to do so because the designated SHPDA finds such replacement or restoration to be inconsistent with the health systems plan of the provider's health service area, the loss is allowable so long as the provider continues to participate in Medicare. In this case, the loss must be capitalized as a deferred charge and amortized over the remaining life of the involuntarily converted asset, or at the rate of $5,000 per year, whichever is greater.

(v) If a gain is realized from an involuntary conversion of depreciable assets, the net amount realized reduces the basis of the restored or replacement asset. If the asset is not restored or replaced, the gain is to be treated in accordance with paragraph (f)(2) of this section.

(7) *Effect on equity capital.* The unrecovered loss entered on the books of the provider as a deferred charge, in accordance with paragraphs (f) (5) and (6) of this section, is not includable in the computation of equity capital under § 413.157.

(8) *Sale of replacement or restored assets.* If a provider sells a replacement or restored asset while participating in the Medicare program or within 1 year immediately following the date on which it terminates its participation in the Medicare program, the unrecovered loss entered on the books of the provider as a deferred charge in accordance with paragraphs (f) (5) and (6) of this section will not be included in determining the gain or loss realized from the sale of the replacement or restored asset. However, if the sale of such asset is made to a related organization, as defined in § 413.17, and the purchasing organization continues as a provider in the Medicare program, the remaining deferred charge representing the unrecovered depreciable basis of the demolished, abandoned or destroyed asset must continue to be amortized over the remaining expected useful life of the replacement or restored asset. If the sale is made to an unrelated organization, further amortization of the deferred charge is not allowed.

(g) *Establishment of cost basis on purchase of facility as an ongoing operation*—(1) *Assets acquired after July 1, 1966 and before August 1, 1970.* The cost basis for the assets of a facility purchased as an ongoing operation after July 1, 1966, and before August 1, 1970, is the lowest of the—

(i) Total price paid for the facility by the purchaser, as allocated to the individual assets of the facility;

(ii) Total fair market value of the facility at the time of the sale, as allocated to the individual assets; or

(iii) Combined fair market value of the individually identified assets at the time of the sale.

(2) *Assets acquired after July 31, 1970.* For depreciable assets acquired after July 31, 1970, in addition to the limitations specified in paragraph (g)(1) of this section, the cost basis of the depreciable assets may not exceed the current reproduction cost depreciated on a straight-line basis over the life of the assets to the time of the sale.

(3) *Transactions other than bona fide.* If the purchaser cannot demonstrate that the sale was bona fide, in addition to the limitations specified in paragraphs (g) (1) and (2) of this section, the purchaser's cost basis may not exceed the seller's cost basis, less accumulated depreciation.

(h) *Intergovernmental transfer of facilities.* The basis for depreciation of assets transferred under appropriate legal authority from one governmental entity to another is as follows:

(1) The historical cost incurred by the present owner in acquiring the asset under a bona fide sale. The historical cost may not exceed the lower of current reproduction cost adjusted for straight-line depreciation over the life of the asset to the time of the purchase of fair market value at the time of the purchase.

(2) The fair market value at the time of donation under a bona fide donation of the asset (subject to the limitations set forth under paragraph (i) of this section). An asset is considered donated when a governmental entity acquires the asset without assuming the functions for which the transferor used the asset or making any payment for it in the form of cash, property, or services.

(3) If neither paragraph (h) (1) nor (2) of this section applies, for example, the transfer was solely to facilitate administration or to reallocate jurisdictional responsibility, or the transfer constituted a taking over in whole or in part of the function of one governmental entity by another governmental entity, the basis for depreciation is—

(i) With respect to an asset on which the transferor has claimed depreciation under the Medicare program, the transferor's basis under the Medicare program prior to the transfer. The method of depreciation used by the transferee may be the same as that used by the transferor, or the transferee may change the method, as permitted under paragraph (d)(2) of this section; or

(ii) With respect to an asset on which the transferor has not claimed depreciation under the Medicare program, the cost incurred by the transferor in acquiring the asset (not to exceed the basis that would have been recognized had the transferor participated in the Medicare program) less depreciation calculated on the straight-line basis over the life of the asset to the time of transfer.

(i) *Basis of assets used under the program and donated to a provider.* If an asset that has been used or depreciated under the program is donated to a provider, the basis of depreciation for the asset is the lesser of the fair market value or the net book value of the asset in the hands of the owner last participating in the program. The net book value of the asset is defined as the depreciable basis used under the program by the asset's last participating owner less the depreciation recognized under the program.

(j) *Limitation on Federal participation for capital expenditures.* The allowance for depreciation is not an allowable cost for certain capital expenditures as described in § 413.161.

(k) *Transactions involving a provider's capital stock*—(1) *Acquisition of capital stock of a provider.* If the capital stock of a provider is acquired, the provider's assets may not be revalued. For example, if Corporation A purchases the capital stock of Corporation B, the provider, Corporation B continues to be the provider after the purchase and Corporation A is merely the stockholder. Corporation B's assets may not be revalued.

(2) *Statutory merger.* A statutory merger is a combination of two or more corporations under the corporation laws of the State, with one of the corporations surviving. The surviving corporation acquires the assets and liabilities of the merged corporation(s) by operation of State law. The effect of a statutory merger upon Medicare reimbursement is as follows:

(i) *Statutory merger between unrelated parties.* If the statutory merger is between two or more corporations that are unrelated (as specified in § 413.17), the assets of the merged corporation(s) acquired by the surviving corporation may be revalued in accordance with paragraph (g) of this section. If the merged corporation was a provider before the merger, then it is subject to the provisions of paragraphs (d)(3) and (f) of this section concerning recovery of accelerated depreciation and the realization of gains and losses. The basis of the assets owned by the surviving corporation are unaffected by the transaction. An example of this type of transaction is one in which Corporation A, a nonprovider, and Corporation B, the provider, are combined by a statutory merger, with Corporation A being the surviving corporation. In such a case the assets of Corporation B acquired by Corporation A may be revalued in accordance with paragraph (g) of this section.

(ii) *Statutory merger between related parties.* If the statutory merger is between two or more related corporations (as specified in § 413.17), no revaluation of assets is permitted for those assets acquired by the surviving corporation. An example of this type of transaction is one in which Corporation A purchase the capital stock of Corporation B, the provider. Immediately after the acquisition of the capital stock of Corporation B, there is a statutory merger of Corporation B and Corporation A, with Corporation A being the surviving corporation. Under these circumstances, at the time of the merger the transaction is one between related parties and is not a basis for revaluation of the provider's assets.

(3) *Consolidation.* A consolidation is the combination of two or more corporations resulting in the creation of a new corporate entity. If at least one of the original corporations is a provider, the effect of a consolidation upon Medicare reimbursement for the provider is as follows:

(i) *Consolidation between unrelated parties.* If the consolidation is between two or more corporations that are unrelated (as specified in § 413.17), the assets of the provider corporation(s) may be revalued in accordance with paragraph (g) of this section.

(ii) *Consolidation between related parties.* If the consolidation is between two or more related corporations (as specified in § 413.17), no revaluation of provider assets is permitted.

§ 413.139 Depreciation: Optional allowance for depreciation based on a percentage of operating costs.

(a) *Principle.* With respect to all assets acquired before 1966, the provider, at its option, may choose an allowance for depreciation based on a percentage of operating costs. The operating costs to be used are the provider's 1965 operating costs or the provider's current year's allowable costs, whichever are the lower. The percentage to be applied is 5 percent starting with the year 1966-67, with such percentage being uniformly reduced by one-half percent each succeeding year. The allowance based on operating costs is in addition to regular depreciation on assets acquired after 1965; however, if the optional allowance is selected, the combined amount of such allowance on pre-1966 assets and the straight-line depreciation on assets acquired after 1965 (including the estimated depreciation on assets held on a rental basis during the current year) may not exceed 6 percent of the provider's allowable cost for the current year.

(b) *Definitions*—(1) *Operating costs.* Operating costs are the total costs incurred by the provider in operating the institution or facility.

(2) *Allowable costs.* Allowable costs are the costs of a provider that are includable under the principles for cost reimbursement. Through application of apportionment methods to the total amount of such allowable costs, the share of a provider's total cost that is attributable to covered services for beneficiaries is determined.

(c) *Application.* If a provider has inadequate historical cost records for pre-1966 depreciable assets, the provider may elect to receive an allowance for depreciation on such assets based on a percentage of operating costs. The optional allowance for depreciation for such assets may be used, however, whether or not a provider has records of the cost of pre-1966 depreciable assets currently in use.

(d) *Allowance based on a percentage of operating costs.* (1) The allowance for depreciation based on a percentage of operating costs is to be computed by applying a specified percentage to a base amount equal to the provider's 1965 total operating costs, without adjustments to these principles or the current year's allowable operating costs, whichever is lower. The percentage to be applied is five for the reporting period that starts before or during 1966-67, four and one-half for the reporting period that begins during 1967-68, and continues to decline annually by equal amounts to become zero in 1976-77.

(2) If used as a base for determining the optional allowance for depreciation, neither the 1965 operating costs nor the current year's allowable costs are to include any actual depreciation, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, or return on equity capital. Such exclusions are to be made only for the purpose of computing the allowance for depreciation based on operating costs. For other purposes, the excluded amounts are recognized in determining allowable costs and for computing the costs of services furnished to Medicare beneficiaries during the reporting period.

(e) *Change to actual depreciation.* (1) A provider that elects this allowance may at any time before 1976 change to actual depreciation on all pre-1966 depreciable assets. In such case, this option is eliminated and the provider can no longer elect to receive an allowance for depreciation based on a percentage of operating costs.

(2) If the provider desires to change to actual depreciation but either has no historical cost records or has incomplete records, the determination of historical cost may be made through appropriate means involving expert consultation with the determination being subject to review and approval by the intermediary.

(f) *Determination of optional allowance based on percentage of operating costs illustrated.* The following illustrates how the provider would determine the optional allowance for depreciation based on operating costs.

Example No. 1. The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 do not include any actual depreciation or rentals on depreciable-type assets. The current year's allowable cost also does not include any allowance in lieu of specific recognition of other costs or return on equity capital.

YEAR 1966

Current year's allowable cost	$1,100,000
Operating cost for 1965[1]	$1,000,000
Percent for determining the allowance	5
Allowance	$50,000

[1] 1965 Operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

YEAR 1967

Current year's allowable cost	$1,200,000
Operating cost for 1965[1]	$1,000,000
Percent for determining the allowance[2]	5
Allowance	$50,000

[1] 1965 Operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1967 allowable cost.

[2] Since the reporting period began during the year 1966-1967 (July 1, 1966–June 30, 1967) 5 percent is the percentage to be used.

YEAR 1968

Operating cost for 1965	$1,000,000
Current year's allowable cost [1]	$900,000
Percent for determining the allowance[2]	4½
Allowance	$40,500

[1] The current year's allowable cost was used in computing the allowance for depreciation based on percentage of operating costs because it was lower than 1965 operating cost.

[2] Since the reporting period began during the year 1967-1968 (July 1, 1967–June 30, 1968) 4½ percent is the percentage to be used.

Example No. 2. **When the provider pays rent for depreciable-type assets rented prior to 1966, the estimated depreciation on such assets must be deducted from the allowance. The following illustration demonstrates how the allowance is determined.**

The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 did not include any actual depreciation, allowance in lieu of specific recognition of other costs, or return on equity capital. However, such costs have been adjusted to exclude estimated depreciation on rented depreciable-type assets.

YEAR 1966

Adjusted current year's allowable cost	$1,100,000
Adjusted operating cost for 1965[1]	$1,000,000
Percent for determining the allowance	5
Allowance	$50,000
Less estimated depreciation for depreciable-type assets rented prior to 1966 on which rental is paid in 1966	$3,000
Adjusted allowance	$47,000

[1] 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

(g) *Limitation on depreciation if optional allowance is used.* This optional allowance only is subject to a limitation based on the provider's total al-

lowable operating cost for the current year. To determine this limitation, compute the sum of the actual depreciation claimed, the allowance based on a percentage of operating costs, and the estimated straight-line depreciation on depreciable-type assets rented after 1965. If this sum exceeds six percent of the provider's current year's allowable cost (exclusive of any actual depreciation claimed, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital), the allowance for depreciation based on a percentage of operating costs is reduced by the amount of excess. In applying this limitation, if the actual depreciation claimed is on an accelerated basis, it must be converted to a straight-line basis only for use in calculating this limitation. It is presumed that pre-1966 assets will not be retired at a greater than normal rate, and the limitation of six percent, as it affects the availability of the allowance, is designed as a safeguard if the presumption is not borne out. If the provider does not elect to use the optional allowance, the combined allowance for depreciation based on costs of pre-1966 assets and those subsequently acquired is not subject to the six percent limitation.

Example No. 1. The following illustration demonstrates how this limitation would be determined.

YEAR 1966

[The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 have been adjusted to exclude actual depreciation, the estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital.]

Adjusted operating cost for 1965	$1,000,000
Percent for determining the allowance	5
In 1966 assets were acquired which produce a straight-line depreciation of	$18,000
Estimated depreciation on assets rented in 1966	$2,000
Adjusted allowable operating cost for 1966	$1,100,000

CALCULATION OF ALLOWANCE FOR DEPRECIATION BASED ON A PERCENTAGE OF OPERATING COSTS

Gross allowance

5 percent times adjusted 1965 operating costs ($1,000,000)	$50,000
Estimated depreciation on assets rented in 1966	2,000
Straight-line depreciation on post-1965 assets	18,000

YEAR 1966—Continued

[The provider keeps its records on a calender year basis. The current year's actual allowable cost and the actual operating cost for 1965 have been adjusted to exclude actual depreciation, the estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital.]

Total	70,000
6 percent of adjusted 1966 allowable operating cost	66,000
Reduction in allowance	4,000
Allowance	50,000
Reduction	4,000
Adjusted allowance	46,000
Total depreciation allowance for 1966 ($18,000 actual depreciation plus $46,000 allowance based on operating cost)	64,000

Assume in this illustration that the provider had elected to use the declining balance method in computing its allowable depreciation and the rental expense for depreciable-type assets was $3,500. In that case, it would include in its 1966 allowable cost not only the $46,000 allowance based on operating costs but also $36,000 (in this instance 2×straight-line rate is used) in actual depreciation and the rental expense of $3,500—or a total of $85,500 covering all its depreciable assets.

§ 413.144 Depreciation: Allowance for depreciation on fully depreciated or partially depreciated assets.

(a) *Principle.* Depreciation on assets being used by a provider at the time it enters into the Medicare program is allowed. This principle applies even though such assets may be fully or partially depreciated on the provider's books.

(b) *Application.* Depreciation is allowable on assets being used at the time the provider enters into the program. This applies even though such assets may be fully depreciated on the provider's books or fully depreciated with respect to other third-party payers. So long as an asset is being used, its useful life is considered not to have ended, and consequently the asset is subject to depreciation based upon a revised estimate of the asset's useful life as determined by the provider and approved by the intermediary. Correction of prior years' depreciation to reflect revision of estimated useful life should be made in the first year of participation in the program unless the provider has used the optional method (§ 413.130), in which case the correction should be made at the time of discontinuing the use of that method. If an asset has become fully depreciated under Medicare, further depreciation is not appropriate or allowable, even though the asset may continue in use.

(c) *Example of an allowance for a fully-depreciated asset.* For example, if a 50-year-old building is in use at the time the provider enters into the program, depreciation is allowable on the building even though it has been fully depreciated on the provider's books. Assuming that a reasonable estimate of the asset's continued life is 20 years (70 years from the date of acquisition), the provider may claim depreciation over the next 20 years—if the asset is in use that long—or a total depreciation of as much as twenty-seventieths of the asset's historical cost.

(d) *Corrections to depreciation.* If the asset is disposed of before the expiration of its estimated useful life, the depreciation would be adjusted to the actual useful life. Likewise, a provider may not have fully depreciated other assets it is using and finds that it has incorrectly estimated the useful lives of those assets. In such cases, the provider may use the corrected useful lives in determining the amount of depreciation, provided such corrections have been approved by the intermediary.

§ 413.149 Depreciation: Allowance for depreciation on assets financed with Federal or public funds.

(a) *Principle.* Depreciation is allowed on assets financed with Hill-Burton or other Federal or public funds.

(b) *Application.* Like other assets (including other donated depreciable assets), assets financed with Hill-Burton or other Federal or public funds become a part of the provider institution's plant and equipment to be used in furnishing services. It is the function of payment of depreciation to provide funds that make it possible to maintain the assets and preserve the capital employed in the production of services. Therefore, irrespective of the source of financing of an asset, if it is used in the providing of services for beneficiaries of the program, payment for depreciation of the asset is, in fact, a cost of the production of those services. Moreover, recognition of this cost is necessary to maintain productive capacity for the future. An incentive for funding of depreciation is provided in these principles by the provision that investment income on funded depreciation is not treated as a reduction of allowable interest expense under § 413.153(a).

§ 413.153 Interest expense.

(a)(1) *Principle.* Necessary and proper interest on both current and capital indebtedness is an allowable cost. However, interest costs are not allowable if incurred as a result of—

(i) Judicial review by a Federal court (as described in § 413.64(j));

(ii) An interest assessment on a determined overpayment (as described in § 405.376 of this chapter); or

(iii) Interest on funds borrowed to repay an overpayment (as described in § 413.64(j) or § 405.376 of this chapter), up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(2) *Exception.* In those cases of administrative or judicial reversal, interest paid on funds borrowed to repay an overpayment is an allowable cost, in accordance with this section.

(b) *Definitions*—(1) *Interest.* Interest is the cost incurred for the use of borrowed funds. Interest on current indebtedness is the cost incurred for funds borrowed for a relatively short term. This is usually for such purposes as working capital for normal operating expenses. Interest on capital indebtedness is the cost incurred for funds borrowed for capital purposes, such as acquisition of facilities and equipment, and capital improvements. Generally, loans for capital purposes are long-term loans.

(2) *Necessary.* Necessary requires that the interest be—

(i) Incurred on a loan made to satisfy a financial need of the provider. Loans that result in excess funds or investments would not be considered necessary;

(ii) Incurred on a loan made for a purpose reasonably related to patient care; and

(iii) Reduced by investment income except if such income is from gifts and grants, whether restricted or unrestricted, and that are held separate and not commingled with other funds. Income from funded depreciation or a provider's qualified pension fund is not used to reduce interest expense. Interest received as a result of judicial review by a Federal court (as described in § 413.64(j)) is not used to reduce interest expense.

(3) *Proper.* Proper requires that interest be—

(i) Incurred at a rate not in excess of what a prudent borrower would have had to pay in the money market existing at the time the loan was made; and

(ii) Paid to a lender not related through control or ownership, or personal relationship to the borrowing organization. However, interest is allowable if paid on loans from the provider's donor-restricted funds, the funded depreciation account, or the provider's qualified pension fund.

(c) *Borrower-lender relationship.* (1) Except as described in paragraph (c)(2) of this section, to be allowable, interest expense must be incurred on indebtedness established with lenders or lending organizations not related through control, ownership, or personal relationship to the borrower. Presence of any of these factors could affect the "bargaining" process that usually accompanies the making of a loan, and could thus be suggestive of an agreement on higher rates of interest or of unnecessary loans. Loans should be made under terms and conditions that a prudent borrower would make in armslength transactions with lending institutions. The intent of this provision is to assure that loans are legitimate and needed, and that the interest rate is reasonable. Thus, interest paid by the provider to partners, stockholders, or related organizations of the provider would not be allowable. If the owner uses his own funds in a business, it is reasonable to treat the funds as invested funds or capital, rather than borrowed funds. Therefore, if interest on loans by partners, stockholders, or related organizations is disallowed as a cost solely because of the relationship factor, the principal of such loans is treated as invested funds in the computation of the provider's equity capital under § 413.157.

(2) Exceptions to the general rule regarding interest on loans from controlled sources of funds are made in the following circumstances. Interest on loans to providers by partners, stockholders, or related organizations made prior to July 1, 1966, is allowable as cost, provided that the terms and conditions of payment of such loans have been maintained in effect without modification subsequent to July 1, 1966. If the general fund of a provider "borrows" from a donor-restricted fund and pays interest to the restricted fund, this interest expense is an allowable cost. The same treatment is accorded interest paid by the general fund on money "borrowed" from the funded depreciation account of the provider or from the provider's qualified pension fund. In addition, if a provider operated by members of a religious order borrows from the order, interest paid to the order is an allowable cost.

(3) If funded depreciation is used for purposes other than improvement, replacement, or expansion of facilities or equipment related to patient care, allowable interest expense is reduced to adjust for offsets not made in prior years for earnings on funded depreciation. A similar treatment is accorded deposits in the provider's qualified pension fund if such deposits are used for other than the purpose for which the fund was established.

(d) *Loans not reasonably related to patient care.* (1) The following types of loans are not considered to be for a purpose reasonably related to patient care:

(i) For loans made to finance acquisition of a facility, that portion of the cost that exceeds—

(A) Historical cost as determined under § 413.134(b); or

(B) The cost basis determined under § 413.134(g); and

(ii) Loans made to finance capital stock acquisitions, mergers, or consolidations for which revaluation of assets is not allowed under § 413.134(k).

(2) In determining whether a loan was made for the purpose of acquiring a facility, we will apply any owner's investment or funds first to the tangible assets, then to the intangible assets other than goodwill, and lastly to the goodwill. If the owner's investment or funds are not sufficient to cover the cost allowed for tangible assets, we will apply funds borrowed to finance the acquisition to the portion of the allowed cost of the tangible assets not covered by the owner's investment, then to the intangible assets other than goodwill, and lastly to the goodwill.

(e) *Limitation on Federal participation for capital expenditures.* The allowance for depreciation is not an allowable cost for certain capital expenditures as described in § 413.161.

§ 413.157 Return on equity capital of proprietary providers.

(a) *Definitions.* For purposes of this section—

"Proprietary provider" means a provider that is organized and operated with the expectation of earning a profit for its owners (as distinguished from a provider that is organized and operated on a nonprofit basis). Proprietary providers may be sole proprietorships, partnerships, or corporations. Effective for cost reporting periods beginning on or after July 6, 1987, the term applies only to proprietary hospitals and SNFs.

(b) *General rule.* A reasonable return on equity capital invested and used in the provision of patient care is paid as an allowance in addition to the reasonable cost of covered services furnished to beneficiaries by proprietary providers.

(1) *Rate of return applicable to proprietary providers for cost reporting periods beginning before July 6, 1987.* Except as provided in paragraphs (b)(2), (b)(3), and (b)(4) of this section, the amount allowable on an annual basis, for cost reporting periods beginning before July 6, 1987, is determined by multiplying the provider's equity capital by a percentage equal to one and one-half times the average of the rates of interest on special issues of public debt obligations issued for purchase by the Medicare Part A Trust Fund for each of the months during the provider's reporting period or portion thereof covered under the program.

(2) *Rate of return for inpatient hospital services furnished by proprietary hospitals.* The rate used in determining the return for inpatient hospital services is a percentage of the average of the rates of interest described in paragraph (b)(1) of this section. The percentages applicable to inpatient hospital services are as follows:

(i) 150 percent for cost reporting periods beginning before April 20, 1983.

(ii) 100 percent for cost reporting periods beginning on or after April 20, 1983 and before October 1, 1986.

(iii) 75 percent for cost reporting periods beginning on or after October 1, 1986 and before October 1, 1987.

(iv) 50 percent for cost reporting periods beginning on or after October 1, 1987 and before October 1, 1988.

(v) 25 percent for cost reporting periods beginning on or after October 1, 1988 and before October 1, 1989.

(vi) Zero percent for cost reporting periods beginning on or after October 1, 1989.

(3) *Rate of return related to proprietary SNFs.* For cost reporting periods beginning on or after October 1, 1985, the rate used in determining the return for SNF's is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(4) *Rate of return related to outpatient hospital services.* (i) For cost reporting periods beginning on or after October 1, 1985, the rate used in determining the return for outpatient hospital services furnished before January 1, 1988 is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) There is no allowance for return for outpatient hospital services furnished on or after January 1, 1988.

(5) *Rate of return for proprietary services of all nonhospital and non-SNF providers.* (i) For cost reporting periods beginning on or after October 1, 1985, but before July 6, 1987, the rate used in determining the return for services of all nonhospital and non-SNF providers is a percentage equal to

the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) For cost reporting periods beginning on or after July 6, 1987, there is no allowance for return on equity capital for nonhospital and non-SNF providers.

(c) *Application*—(1) *Computation of equity capital*. For purposes of computing the allowable return, the provider's equity capital means—

(i) The provider's investment in plant, property, and equipment related to patient care (net of depreciation) and funds deposited by a provider who leases plant, property, or equipment related to patient care and is required by the terms of the lease to deposit such funds (net of noncurrent debt related to such investment or deposited funds); and

(ii) Net working capital maintained for necessary and proper operation of patient care activities. However, debt representing loans from partners, stockholders, or related organizations on which interest payments would be allowable as costs but for the provisions of § 413.153(b)(3)(ii), is not subtracted in computing the amount of equity capital in order that the proceeds from such loans be treated as part of the provider's equity capital. In computing the amount of equity capital upon which a return is allowable, investment in facilities is recognized on the basis of the historical cost, or other basis, used for depreciation and other purposes under Part A of Medicare.

(2) *Acquisitions after July 1970*. With respect to a facility or any tangible assets of a facility acquired on or after August 1, 1970, the excess of the price paid for such facility or such tangible assets over the historical cost, as defined in § 413.134(b), or the cost basis, as determined under § 413.134(g) (whichever is appropriate), is not includable in equity capital, and loans made to finance such excess portion of the cost of such acquisitions (see § 413.153(d)) are excluded in computing equity capital.

(3) *Acquisitions prior to August 1970*. With respect to a facility or any tangible assets of a facility acquired before August 1970, the excess of the price paid for such facility or assets over the fair market value of tangible assets at the time of purchase is includable in equity capital to the extent that it is reasonable except that the cumulative allowable return for such excess may not exceed 100 percent of such excess. For purposes of this section, the cumulative allowable return means the sum of the allowable rate of return on equity capital for all months starting from August 1, 1970. For example, if the allowable rates of return on equity capital for a provider are 9 percent for the first year (and such year started August 1, 1970), 8.5 percent for the second year, and 10.5 percent for the third year, the cumulative allowable return at the end of the third year would be 28 percent. After the cumulative allowable return equals 100 percent, the inclusion in equity capital of the excess is no longer allowable.

(4) *Computation of return on equity capital*. For purposes of computing the allowable return, the amount of equity capital is the average investment during the reporting period. The rate of return allowed, as derived from time to time based upon interest rates in accordance with this principle, is determined by HCFA and communicated through intermediaries. Return on investment as an element of allowable costs is subject to apportionment in the same manner as other elements of allowable costs.

Example of calculation of cumulative allowable return. X purchased a provider on July 1, 1969, paying $100,000 in excess of the fair market value of the assets acquired. Provider X files its cost report on a calendar-year basis. The allowable rate of return on equity capital for August 1, 1970-December 31, 1970 (4.538 percent), is obtained by multiplying the allowable rate of return for the period ending December 31, 1970 (10.891) by $\frac{5}{12}$ (a fraction of which the numerator is the number of months from August 1, 1970, to the end of the cost-reporting period and the denominator is the number of months in the cost-reporting period). The cumulative allowable return for Provider X for the period August 1, 1970-December 31, 1973, (32.367 percent) is computed as follows:

Cost reporting year ending	Rate of return on equity capital (percent)
Dec. 31, 1970	4.538
Dec. 31, 1971	8.969
Dec. 31, 1972	8.891
Dec. 31, 1973	9.969
Total	32.367

(The $100,000 paid in excess of the fair market value of the assets acquired is included in equity capital until the sum of the allowable rate of return on equity capital equals 100 percent. Of course, no portion of the $100,000 may be amortized as an allowable cost or is otherwise allowable for any program reimbursement purposes other than for determining the provider's equity capital.

(5) *Unapproved capital expenditures.* Effective with respect to any capital expenditure, the obligation for which is incurred after December 31, 1972, or after the effective date of an agreement executed between a State and the Secretary pursuant to section 1122 of the Act, whichever date is later (and subject to the exceptions in § 413.161(c)), a provider's investment in plant, property, and equipment related to patient care, and funds deposited by a provider which leases plant, property, or equipment related to patient care that are found to be expenditures which have not been submitted to the designated planning agency as required or have been determined to be inconsistent with health facility planning requirements (as described in §§ 100.101 through 100.109 of this title), are not included in the provider's equity capital for computing the allowance for a reasonable return on equity capital.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 52 FR 32921, Sept. 1, 1987; 53 FR 12017, Apr. 12, 1988]

§ 413.161 Nonallowable costs related to certain capital expenditures.

(a) *Principle.* Effective with respect to any capital expenditure, as defined in Part 100 of this title, the obligation for which is incurred after December 31, 1972, or after the effective date of an agreement executed between a State and the Secretary pursuant to section 1122 of the Act, whichever date is later, the depreciation, interest on borrowed funds, return on equity capital (in the case of certain proprietary providers), and any other costs attributable to such capital expenditure, for which the Secretary has determined that such proposed capital expenditure has not been submitted to the designated planning agency as required, or that it has been determined by such agency to be inconsistent with the standards, plans, or criteria developed to meet the need for adequate health care facilities (as defined in §§ 100.101 through 100.109 of this title) are not allowable. Other costs related to such capital expenditures include title fees; permit and license fees; broker commissions; architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, or notes; and other costs incurred for borrowing funds. The reasonable costs incurred by a provider for studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisitions, improvement, expansion, or replacement of the plant and equipment that are conducted to enable the provider to properly determine whether the proposed capital expenditure would be in compliance with the standards, plans, or criteria developed by the designated planning agency are allowable, except if the provider makes the capital expenditure and does not receive the required approval.

(b) *Applicability.* Under the principle specified in paragraph (a) of this section, any costs related to capital expenditures, the obligation for which was incurred by or on behalf of a provider subsequent to 1972 (except as described in paragraph (c) of this section), are not allowable if the Secretary has determined that the capital expenditures have not been submitted to the designated planning agency as required or that they have been determined to be inconsistent with the standards, plans, or criteria developed by the designated planning agency or other health planning agency in the State to meet the need for adequate health care facilities in the area covered by the plan or plans so developed (see §§ 100.101 through 100.109 of this title). Costs claimed by a provider in connection with capital assets that are donated or transferred to a provider are also subject to the application of such principle. Such principle also applies to the reasonable equivalent of that portion of any rental expense incurred pursuant to a lease or a comparable arrangement (and to any amounts deposited under the terms of such a lease or comparable arrangement in computing the return on equity capital) that would have been excluded had the provider acquired such a facility or equipment by purchase. The amounts excluded are not subject to reimbursement under any other provisions of Medicare.

(c) *Exceptions.* The limitation on recognition of costs attributable to capital expenditures discussed in this section does not apply to the following:

(1) A provider furnishing health care services as of December 18, 1970, that on such date was committed to a formal plan of expansion or replacement, with respect to such expenditures as may be made or such obligations as may be incurred for capital items included in such plan for which preliminary expenditures toward the plan of expansion or replacement (including payments for studies, surveys, designs, plans, working drawings, specifications, and site acquisition, essential to the acquisition, improvement, expansion, or replacement of the health care facility or equipment concerned) of $100,000 or more, had been made during the three-year period ending December 17, 1970.

(2) Christian Science sanatoria operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts.

(3) Capital expenditures the obligations for which were incurred by or on behalf of a provider prior to 1973.

(4) Capital expenditures the exclusion of which the Secretary has determined would—

(i) Discourage the operation or expansion of a provider that has demonstrated its capability of providing comprehensive health care services efficiently, effectively, and economically; or

(ii) Otherwise be inconsistent with the effective organization and delivery of health services or the effective administration of Title V, XVIII, or XIX of the Act.

(d) *Appeals.* See § 405.1890 of this chapter for appeal rights of a provider or other person dissatisfied with a determination under section 1122 of the Act (42 U.S.C. 1320a-1).

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21226, June 4, 1987]

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

§ 413.170 Payments for covered outpatient maintenance dialysis treatments.

(a) *Basis and purpose.* This section implements section 1881 (b)(2) and (b)(7) of the Act by—

(1) Setting forth the principles and authorities under which HCFA is authorized to establish a prospective reimbursement system for outpatient maintenance dialysis furnished in or under the supervision of an ESRD facility approved under Subpart U of Part 405 of this chapter (referred to as "facility" in this section). For purposes of this section and § 413.174, outpatient maintenance dialysis means outpatient dialysis, home dialysis and self-dialysis, and home dialysis training as defined in § 405.2102 (f)(2)(ii), (f)(2)(iii), and (f)(3) of this chapter, and includes all items and services specified in § 405.231 (o) and (p) of this chapter.

(2) Providing for procedures and criteria under which a facility may receive an exception to the prospective payment rates established under this section; and

(3) Establishing procedures and criteria for a facility to appeal its reimbursement under the prospective reimbursement system.

(b) *Principles of prospective reimbursement.* (1) Under prospective reimbursement, payments for outpatient maintenance dialysis are based on rates set prospectively by HCFA.

(2) All approved ESRD facilities must accept the prospective payment rates established by HCFA as payment in full for covered outpatient maintenance dialysis.

(3) HCFA will publish the methodology used to establish rates and changes in payment rates in the FEDERAL REGISTER, as provided in paragraph (i)(2) of this section.

(c) *Prospective rates for hospital-based and independent ESRD facilities.* (1) In accordance with section 1881(b)(7) of the Act, HCFA will establish prospective rates by a methodology that—

(i) Differentiates between hospital-based facilities and independent ESRD facilities;

(ii) Effectively encourages efficient delivery of dialysis services; and

(iii) Provides incentives for increasing the use of home dialysis.

(2) For purposes of rate-setting and reimbursement under this section, HCFA will consider any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph is an initial determination under § 405.1502 of this chapter.

(3) For purposes of rate-setting and reimbursement under this section, HCFA will determine that a facility is hospital-based if the—

(i) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. All authority in management flows from this governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(ii) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(iii) Facility personnel policies and practices conform to those of the hospital;

(iv) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(v) Facility and hospital are financially integrated, as evidenced by the cost report, which must reflect allocation of overhead to the facility through the required step-down methodology.

(4) In determining whether a facility is hospital-based, HCFA will not consider—

(i) An agreement between a facility and a hospital concerning patient referral;

(ii) A shared service arrangement between a facility and a hospital; or

(iii) The physical location of a facility on the premises of a hospital.

(d) *Amount of payments.* (1) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the treatment, the intermediary will pay the facility 80 percent of its prospective payment rate.

(2) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the treatment, the intermediary will subtract the amount applicable to the deductible from the facility's prospective rate, and will pay the facility 80 percent of the remainder, if any.

(e) *Bad debts.* (1) HCFA will reimburse each facility its allowable Medicare bad debts, up to the facility's costs as determined under Medicare principles, in a single lump sum at the end of the facility's cost reporting period.

(2) A facility must attempt to collect deductible and coinsurance amounts owed by beneficiaries before requesting reimbursement from HCFA for uncollectible amounts. Section 413.80 specifies the efforts facilities must make.

(3) A facility must request reimbursement for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list of all specific noncollections related to covered services.

(f) *Procedures for requesting exceptions to payment rates.* (1) All payments for outpatient maintenance dialysis furnished at or through facilities will be made on the basis of prospective payment rates, without exemption.

(2) If a facility projects on the basis of prior year cost and utilization trends that it will have an allowable cost per treatment higher than its prospective rate set under this section, and if these excess costs are attributable to factors related to one or more of the criteria in paragraph (g) of this

section, the facility may request HCFA to approve an exception to that rate and set a higher prospective payment rate.

(3) This higher payment rate will be subject to the rules governing the amount of payment in paragraph (d) of this section.

(4) A facility must request an exception to its payment rate within 180 days after—

(i) It is notified of its prospective payment rate; or

(ii) An extraordinary event with substantial cost effects, as described in paragraph (g)(4) of this section.

(5) The facility is responsible for demonstrating to HCFA's satisfaction that the requirements of this section, including the criteria in paragraph (g) of this section, are met in full. That is, the burden of proof is on the facility to show that one or more of the criteria are met, and that the excessive costs are justifiable under the reasonable cost principles set forth in this part. The burden of proof is not on HCFA to show that the criteria are not met, and that the facility's costs are not allowable.

(6) If requesting an exception to its payment rate, a facility must submit to HCFA its most recently completed cost report as required under § 413.174, and whatever statistics, data, and budgetary projections are determined by HCFA to be needed to determine if the exception is approvable. HCFA may audit any cost report or other information submitted. The materials submitted to HCFA must—

(i) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(ii) Show that all of the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(iii) Show that the elements of excessive cost are specifically attributable to one or more conditions specified by the criteria set forth in paragraph (g) of this section; and

(iv) Specify the amount of additional reimbursement per treatment the facility believes is required in order to recover its justifiable excess costs.

(7) HCFA will accept an exception request on the date that HCFA concludes that it has received all materials necessary to determine if the exception is approvable.

(8) In determining the facility's payment rate under the exception process, HCFA will exclude all costs that are not allowable under the reasonable cost principles set forth in this part.

(9) Except for exceptions approved under paragraph (g)(4) of this section, a prospective exception payment rate approved by HCFA will apply for the period from the date the exception request was accepted until the earlier of the—

(i) Date the circumstances justifying the exception rate no longer exist; or

(ii) End of the 12-month period during which the announced rate was to apply.

(10) A prospective exception payment rate approved by HCFA under paragraph (g)(4) of this section will apply from the date of the extraordinary event until the end of the 12-month period during which the announced rate was to apply, unless HCFA determines that another date is more appropriate. If HCFA does not extend the exception period, and the facility believes that it continues to require an exception to its rate, the facility must reapply in accordance with paragraph (f) of this section.

(g) *Criteria for approval of exception requests.* HCFA may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates with convincing objective evidence that its total per treatment costs are reasonable and allowable under § 413.174, and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(1) *Atypical service intensity (patient mix).* A substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. The facility is able to demonstrate clearly that these services, pro-

cedures or supplies and its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix. Examples that may qualify under this criterion are more intense dialysis services that are medically necessary for patients such as—

(i) Patients who have been referred from other facilities on a temporary basis for more intense care during a period of medical instability, and who return to the original facility after stabilization;

(ii) Pediatric patients, who require a significantly higher staff-to-patient ratio than typical adult patients; or

(iii) Patients with medical conditions that are not commonly treated by ESRD facilities, and that complicate the dialysis procedure.

(2) *Isolated essential facility.* The facility is the only supplier of dialysis in its geographical area, its patients cannot obtain dialysis services elsewhere without substantial additional hardship, and its excess costs are justifiable. HCFA will consider local permanent residential population density, typical local commuting distances for medical services, volume of treatments, and dialysis facility usage by area residents other than the applying facility's patients, in determining whether an exception requested on this basis is approvable.

(3) *Education costs.* The facility has excess costs attributable to an approved nursing education program or intern-resident program as specified in § 413.85. The amount of the increase in the facility's rate is limited to the amount that is properly allocated to the outpatient dialysis department, and to what is reasonable when compared to the costs of other similar facilities that have educational programs.

(4) *Extraordinary circumstances.* The facility incurs excess costs beyond its control due to a fire, earthquake, flood, or other natural disaster. HCFA will not recognize such costs in cases when a facility chose not to maintain adequate insurance protection against such losses (through the purchase of insurance, the maintenance of a self-insurance program, or other equivalent alternative) or chose not to file a claim for losses covered by insurance, or not to utilize its self-insurance program.

(5) *Self-dialysis training costs.* The facility incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for such training sessions.

(6) *Frequency of dialysis.* The facility has a substantial proportion of patients who dialyze less frequently than three times per week. Per treatment payment rates granted under this exception will be no more than the amount that results in weekly reimbursement per patient equal to three times the facility's prospective composite rate, exclusive of any exception amounts.

(h) *Appeals.* (1) *Appeals under section 1878 of the Act.* A facility that disputes the amount of its allowable Medicare bad debts reimbursed by HCFA under paragraph (e) of this section may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) in accordance with Subpart R of Part 405 of this chapter.

(2) *Other appeals.* A facility that has requested higher payment per treatment in accordance with paragraph (f) of this section may request a review from the intermediary or the PRRB if HCFA has denied the request in whole or in part. In such a case, the procedure in Subpart R of Part 405 of this chapter will be followed to the extent that it is applicable. The PRRB, subject to review by the Administrator under § 405.1875 of this chapter, will have the authority to determine whether the HCFA action under review conformed to the provisions of paragraph (f).

(3) *Procedure.* (i) The facility must request a review within 180 days of the date of the decision on which review is sought.

(ii) The facility may not submit to the intermediary or the PRRB any additional information or cost data that were not submitted to HCFA at the time the facility requested an exception to its prospective payment rate.

(4) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under Subpart R of

Part 405 of this chapter for the appeals described in paragraph (h)(2) of this section—

(i) The amount in controversy per treatment will be determined by subtracting the amount of program payment from the amount the facility requested under paragraph (f) of this section; and

(ii) The total amount in controversy will be calculated by multiplying the amount per treatment by the projected estimated number of treatments for the exception request period (as specified in paragraphs (f) (7) and (8) of this section).

(i) *Notification of changes in rate-setting methodologies and payment rates.* (1) HCFA or the facility's intermediary will notify each facility annually of its payment rate. This notice will include changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(2) Changes in payment rates resulting from incorporation of updated cost data, or general revisions of geographic labor cost adjustment factors, will be announced by notice published in the FEDERAL REGISTER without opportunity for prior public comment. Other revisions of the rate-setting methodology will be published in the FEDERAL REGISTER in accordance with the Department's established rule-making procedures.

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986]

§ 413.174 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and scope.* This section implements section 1881(b)(2)(B)(i) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities approved under Subpart U of Part 405 of this chapter. The records and reports will enable HCFA to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a)(1).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate HCFA-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with § 413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis services, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

(i) Are not related to patient care for outpatient maintenance dialysis;

(ii) Are for services or items specifically not reimbursable under the program;

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

(iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

(i) Section 413.157, Return on equity capital of proprietary providers;

(ii) Section 413.178, Reimbursement of OPAs and histocompatibility laboratories;

(iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and

(iv) Sections 413.64, Payment to providers, and §§ 413.13, 413.30, 413.35, 413.40, 413.74, 413.56, and §§ 405.465

through 405.482 of this chapter, Effect of principles.

§ 413.178 Reimbursement of independent organ procurement organizations and histocompatibility laboratories.

(a) *Principle.* Covered services furnished after September 30, 1978 by organ procurement organizations (OPOs) and histocompatibility laboratories in connection with kidney acquisition and transplantation will be reimbursed under the principles for determining reasonable cost contained in this part. Services furnished by freestanding OPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, will be reimbursed by making an interim payment to the transplant hospitals using these services and by making a retroactive adjustment, directly with the OPO or laboratory, based upon a cost report filed by the OPO or laboratory. (The reasonable costs of services furnished by hospital based OPOs or laboratories will be reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* For purposes of this section:

"Freestanding"—An OPO or a histocompatibility laboratory is freestanding unless it—

(i) Performs services exclusively for one hospital;

(ii) Is subject to the control of the hospital in regard to the hiring, firing, training and paying of employees; and

(iii) Is considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

"Histocompatibility laboratory" means a laboratory meeting the standards and providing for kidneys or other organs the services set forth in § 405.2171(d) of this chapter.

"OPO" means an organization that meets the definition in § 485.302 of this chapter.

(c) *Agreements with independent OPOs and laboratories.* (1) Any freestanding OPO or histocompatibility laboratory that wishes to have the cost of its pretransplant services reimbursed under the Medicare program must file an agreement with HCFA under which the OPO or laboratory agrees—

(i) To file a cost report in accordance with § 413. 24(f) within three months after the end of each fiscal year;

(ii) To permit HCFA to designate an intermediary to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPO or laboratory and to make a determination of reasonable cost based upon the cost report filed by the OPO or laboratory;

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

(iv) To pay to HCFA amounts that have been paid by HCFA to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the OPO or laboratory; and

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an OPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c)(1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Hospitals eligible to receive Medicare reimbursement for renal transplantation will be paid for the pretransplantation services of a freestanding OPO or histocompatibility laboratory that has an agreement with the Secretary under paragraph (c) of this section, on the basis of an interim rate established by an intermediary for that OPO or laboratory.

(2) The interim rate will be based on the average cost per service incurred by an OPO or laboratory, during its previous fiscal year, associated with procuring a kidney for transplantation. This interim rate may be adjusted if necessary for anticipated cost changes. If there is not adequate cost data to determine the initial interim rate, it will be determined according to

the OPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made on the basis of the interim rate will be reconciled directly with the OPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all freestanding OPOs and histocompatibility laboratories shall be disseminated to all transplant hospitals and intermediaries.

(e) *Retroactive adjustment.* (1) *Cost reports.* Information provided in cost reports by freestanding OPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in paragraphs (a) through (e) of § 413.24. These cost reports must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services, and any other data necessary to enable the intermediary to make a determination of the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by a freestanding OPO or histocompatibility laboratory will be reviewed by the intermediary and a new interim reimbursement rate for the succeeding fiscal year will be established based upon this review. A retroactive adjustment in the amount paid under the interim rate will be made in accordance with § 413.64(f). If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment will be made directly between the intermediary and the OPO or laboratory.

(f) For services furnished on or after April 1, 1988, no payment may be made for services furnished by an OPO that does not meet the requirements of Part 485, Subpart D of this chapter.

(g) *Appeals.* Any OPO or histocompatibility laboratory that disagrees with an intermediary's cost determination under this section is entitled to an intermediary hearing, in accordance with the procedures contained in §§ 405.1811 through 405.1833, if the amount in controversy is $1,000 or more.

[53 FR 6548, Mar. 1, 1988; 53 FR 9145, Mar. 21, 1988; 53 FR 18987, May 26, 1988]

PART 416—AMBULATORY SURGICAL SERVICES

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AUTHORITY: Secs. 1102, 1832(a)(2), 1833, 1863 and 1864 of the Social Security Act (42 U.S.C. 1302, 1395k(a)(2), 1395l, 1395z and 1395aa).

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 416.1 Scope.

This part establishes the requirements for coverage and reimbursement of certain ambulatory surgical services under the Medicare program, authorized under sections 1832(a)(2) and 1833 of the Act.

§ 416.2 Definitions.

As used in this part:

"*Ambulatory surgical center*" or "ASC" means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with HCFA under Medicare to participate as an ASC, and meets the conditions set forth in Subpart B of this part.

"*Covered surgical procedures*" means those surgical and other medical procedures which meet the criteria specified in this part and are published by HCFA in the FEDERAL REGISTER.

§ 416.3 Expenses not subject to deductible or coinsurance.

Notwithstanding any other provisions in this chapter, expenses for services covered under this part are not subject to the supplementary medical insurance benefits deductible or coinsurance requirements for—

(a) Physicians' services (including pre- and post-operative services), when the physician accepts assignment as described in §§ 424.55 and 424.56 of this chapter and provides services in connection with a covered surgical procedure, as specified in § 416.65, that is performed in a participating ASC, on an outpatient basis in a hospital or in a hospital-affiliated ambulatory surgical center; or

(b) Facility services as described in § 416.61 furnished in connection with surgical procedures as specified in § 416.65 when those procedures are performed in a participating ASC.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988]

Subpart B—Ambulatory Surgical Centers: Coverage and Benefits

§ 416.20 Basis and purpose.

This subpart implements sections 1832(a)(2) and 1833 of the Act, with respect to—

(a) The conditions that an ASC must meet to participate in the Medicare program (conditions for coverage); and

(b) The scope of benefits covered in an ASC.

CONDITIONS FOR COVERAGE

§ 416.25 Basic requirements and procedures.

(a) *Eligible facilities.* Participation as an ASC is limited to those facilities that meet the definition in § 416.2.

(b) *Survey of ASCs.* (1) Unless the ASC is deemed to be in compliance with the conditions for coverage (see § 416.39(b) for deemed compliance), the ASC must be surveyed to ascertain compliance with the requirements in §§ 416.40–416.49.

(2) HCFA will survey deemed ASCs on a sample basis as part of HCFA's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If HCFA determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this subpart, it will send to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC.* If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with HCFA.

(e) *Acceptance by HCFA.* If HCFA accepts the agreement filed by the ASC, it will return to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights.* If HCFA refuses to enter into an agreement or if HCFA terminates an agreement, the ASC is entitled to a hearing in accordance with Part 498 of this chapter.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 22454, June 12, 1987]

§ 416.30 Terms of agreement with HCFA.

As part of the agreement under § 416.25(d), the ASC must agree to the following:

(a) *Compliance with coverage conditions.* The ASC agrees to meet the requirements regarding conditions for coverage as specified in § 416.39 and to report promptly to HCFA any failure to do so.

(b) *Charges to beneficiaries.* The ASC agrees not to charge the beneficiary or any other person for items or services for which the beneficiary is entitled to have payment made under the provisions of this subpart (or for which the beneficiary would have been entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter).

(c) *Refunds to beneficiaries.* (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, "money incorrectly collected" means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with HCFA is in effect.

(d) *Furnishing information.* The ASC agrees to furnish to HCFA, if requested, information necessary to establish payment rates specified in §§ 416.120-416.130 in the form and manner that HCFA requires.

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures as specified in § 416.85. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 (when an individual dies before assigning payment).

(f) *ASCs operated by a hospital.* In ASCs operated by a hospital—

(1) The agreement is made effective prospectively on the first day of the Medicare cost reporting period of the hospital with which the ASC is affiliated; and

(2) The ASC participates and is reimbursed only as an ASC, without the option of converting to or being reimbursed as a hospital outpatient department or hospital-affiliated ambulatory surgical center, unless HCFA determines there is good cause to do otherwse.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hospital's cost report.

(g) *Additional provisions.* The agreement may contain any additional provisions that HCFA finds necessary or desirable for the efficient and effective administration of the Medicare program.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 416.35 Termination of agreement.

(a) *Termination by the ASC*—(1) *Notice to HCFA.* An ASC that wishes to terminate its agreement must send HCFA written notice of its intent.

(2) *Date of termination.* The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to HCFA, HCFA may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) HCFA may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Voluntary termination.* If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) *Termination by HCFA*—(1) *Cause for termination.* HCFA may terminate an agreement if it determines that the ASC—

(i) No longer meets the conditions for coverage as specified under § 416.39; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of Subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) *Notice of termination.* HCFA will send notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the ASC.* An ASC may appeal the termination of its agreement in accordance with the provisions set forth in Part 498 of this chapter.

(c) *Effect of termination.* Payment will not be available for ASC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination shall be given to the public, through publication in local newspapers by—

(1) The ASC, after HCFA has approved or set a termination date; or

(2) HCFA, when it has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by HCFA.* When an agreement with an ASC is terminated by HCFA, the ASC may not file another agreement to participate in the Medicare program unless HCFA—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 22454, June 12, 1987]

§ 416.39 Conditions for coverage—General provisions.

(a) An ASC must maintain compliance with the conditions set forth in §§ 416.40 through 416.49.

(b) HCFA may deem an ASC to be in compliance with any or all of the conditions set forth in §§ 416.40 through 416.49 if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State Agency, that HCFA determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to HCFA, of the findings of the accreditation survey.

§ 416.40 Condition for coverage—Compliance with State licensure law.

The ASC must comply with State licensure requirements.

§ 416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. *Standard: Hospitalization.* The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 22041, June 17, 1986]

§ 416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) *Standard: Anesthetic risk and evaluation.* A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist, a supervised trainee in an approved educational program, or an anesthesia assistant. In those cases where a non-physician administers the anesthesia, the anesthetist must be under the supervision of the operating physician. Anesthesia assistants must have successfully completed a four year educational program for physicians' assistants that includes two years of specialized academic and clinical training in anesthesia.

(c) *Standard: Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

§ 416.43 Condition for coverage—Evaluation of quality.

The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

§ 416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) *Standard: Safety from fire.* (1) Except as provided in paragraphs (b)(2) and (3) of this section, the ASC must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference)[1] that are applicable to ambulatory surgical centers.

(2) In consideration of a recommendation by the State survey agency, HCFA may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) Any ASC that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, so long as the ASC continues to remain in compliance with that edition of the Life Safety Code.

(c) *Standard: Emergency equipment.* Emergency equipment available to the operating rooms must include at least the following:

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[1] See footnote to § 405.1134(a) of this chapter.

(1) Emergency call system.

(2) Oxygen.

(3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.

(4) Cardiac defibrillator.

(5) Cardiac monitoring equipment.

(6) Thoracotomy set.

(7) Tracheostomy set.

(8) Laryngoscopes and endotracheal tubes.

(9) Suction equipment.

(10) Emergency drugs and supplies specified by the medical staff.

(d) *Standard: Emergency personnel.* Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988]

§ 416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) *Standard: Reappraisals.* Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(c) *Standard: Other practitioners.* If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

§ 416.46 Condition for coverage—Nursing services.

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

§ 416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) *Standard: Organization.* The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) *Standard: Form and content of record.* The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

(1) Patient identification.

(2) Significant medical history and results of physical examination.

(3) Pre-operative diagnostic studies (entered before surgery), if performed.

(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

(5) Any allergies and abnormal drug reactions.

(6) Entries related to anesthesia administration.

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis.

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

§ 416.49 Condition for coverage—Laboratory and radiologic services.

The ASC must have procedures for obtaining routine and emergency laboratory and radiologic services, from Medicare approved facilities, to meet the needs of patients.

SCOPE OF BENEFITS

§ 416.60 Reimbursable services: General provision.

Ambulatory surgical center services reimbursable under this subpart are facility services, furnished in connection with covered surgical procedures, to Medicare beneficiaries by an ASC that has an agreement with HCFA.

§ 416.61 ASC facility services: Scope.

(a) ASC facility services are items and services furnished by an ASC in connection with a covered surgical procedure as specified under § 416.65, furnished to a Medicare beneficiary. These items and services are those which would otherwise be covered under Medicare if furnished on an inpatient or outpatient basis in a hospital in connection with the covered surgical procedure.

(b) ASC facility services do not include items and services for which payment may be made under other provisions of Part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices, ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home.

(c) ASC facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of ASC facilities;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

§ 416.65 Covered surgical procedures.

Covered surgical procedures are those procedures that meet the standards described in paragraphs (a) and (b) of this section and are included in the list published in accordance with paragraph (c) of this section.

(a) *General standards.* Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under § 405.310 of this chapter.

(b) *Specific standards.* (1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

(3) Covered surgical procedures may not be of a type that—

(i) Generally result in extensive blood loss;

(ii) Require major or prolonged invasion of body cavities;

(iii) Directly involve major blood vessels; or

(iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* HCFA will publish in the FEDERAL REGISTER a list of covered surgical procedures and revisions as appropriate.

§ 416.75 Performance of listed surgical procedures on an inpatient hospital basis.

The inclusion of any procedure as a covered surgical procedure under § 416.65 does not preclude its coverage in an inpatient hospital setting under Medicare.

Subpart C—Payment for Ambulatory Surgical Services

§ 416.100 Basis and purpose.

This subpart implements sections 1832(a)(2) and 1833 of the Act with respect to Medicare payment for ambulatory surgical services furnished in connection with covered surgical procedures performed in a participating ASC, on an outpatient basis in a hospital or in a hospital-affiliated ambulatory surgical center.

§ 416.110 Payment for physicians' services furnished in connection with covered surgical procedures.

Payment for physicians' services (including all pre- and post-operative services) will be made at 100 percent of the reasonable charge (or 100 percent of the reasonable cost, in the case of a health maintenance organization reimbursed under section 1876 of the Act) for those services if—

(a) The services are furnished in connection with a covered surgical procedure as specified in § 416.65;

(b) The surgical procedures are performed in a participating ASC, on an outpatient basis in a hospital or in a hospital-affiliated ambulatory surgical center; and

(c) The physician accepts assignment for those services (see §§ 424.55 and 424.56 of this chapter).

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988]

§ 416.120 Payment for facility services.

Payment for facility services furnished in connection with surgical procedures as specified in § 416.65 will be made as follows:

(a) *Hospital outpatient department.* Payment will be in accordance with Part 413 of this chapter.

(b) *Hospital-affiliated ambulatory surgical center (HAASC).* Payment will be in accordance with Part 413 of this chapter if—

(1) The HAASC is an integral and subordinate part of a hospital;

(2) The HAASC is operated with other departments of the hospital under common licensure, governance and professional supervision; and

(3) The HAASC is not a Medicare participating ASC.

(c) *ASC.* Payment will be based on a prospectively determined rate. This rate will cover the cost of services such as supplies, nursing services, equipment, etc., as specified in § 416.61. The rate will not cover physician's services, or other medical services covered under section 1861(s) of the Act (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedure. These services may be billed separately and paid on a reasonable charge basis.

(1) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment will be 100 percent of the prospectively determined rate for the procedure.

(2) If more than one covered surgical procedure is furnished to a beneficiary in a single operative session, payment will be made at 100 percent of the prospectively determined rate for the procedure with the highest reimbursement rate. Other covered surgical procedures furnished in the same session will be reimbursed at 50 percent of the prospectively determined rate for each of those procedures.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 34831, Sept. 30, 1986]

§ 416.125 ASC facility services payment rate.

(a) The payment rate will be equal to a prospectively determined standard overhead amount per procedure which is based on an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment rate must result in substantially less Medicare expenditures than would have been paid under the program had the procedure been performed on an inpatient basis in a hospital.

§ 416.130 Publication of revised payment methodologies.

Whenever HCFA proposes to revise the payment rate for ASCs, HCFA will publish a notice in the FEDERAL REGISTER describing the revision. The notice will also explain the basis on which the rates were established. After reviewing public comments, HCFA will publish a notice establishing the rates authorized by this section. In setting these rates, HCFA may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

§ 416.140 Reporting requirements.

(a) HCFA will periodically conduct a sample survey of ASCs participating in the program to collect data for analysis or re-evaluation of the payment rates. Such a survey will be conducted no more frequently than annually. HCFA will notify by mail the ASCs randomly selected to participate in each survey, of their selection and the appropriate form and content of the report.

(1) If the facility does not submit an adequate report in response to HCFA's survey request, HCFA may terminate the agreement to participate in the Medicare program as an ASC.

(2) HCFA may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by HCFA, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from HCFA submit, in the form and detail as may be required by HCFA, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(ii) Their customary charges for each surgical procedure furnished for the period.

§ 416.150 Beneficiary appeals.

A beneficiary (or ASC as his or her assignee) may request a hearing by a carrier (subject to the limitations and conditions set forth in Part 405, Subpart H of this chapter) if the beneficiary or the ASC—

(a) Is dissatisfied with a carrier's denial of a request for payment made on his or her behalf by an ASC;

(b) Is dissatisfied with the amount of payment; or

(c) Believes the request for payment is not being acted upon with reasonable promptness.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

Subpart A—Federally Qualified Health Maintenance Organizations

Sec.

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AUTHORITY: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1871, 1874, and 1876 of the Social Security Act (42 U.S.C. 1302, 1395l(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, and 1395mm); sec. 114(c) of Pub. L. 97-248 (42 U.S.C. 1395mm note); 31 U.S.C. 9701; and secs. 215 and 1301 through 1318 of the Public Health Service Act (42 U.S.C. 216 and 300e through 300e-17), unless otherwise noted.

Subpart A—Federally Qualified Health Maintenance Organizations

SOURCE: 45 FR 72528, Oct. 31, 1980, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

Requirements for a Health Maintenance Organization

§ 417.100 Definitions.

As used in this subpart: "the Public Health Service Act" means the Public Health Service Act.

"Basic health services" means health services described in § 417.101(a).

"Community rating system" means a system of fixing rates of payments for health services which meets the requirements of § 417.104(a)(3).

"Comprehensive health services" means as a minimum the following services which may be limited as to time and cost:

(1) Physician services (§ 417.101(a)(1));

(2) Outpatient services and inpatient hospital services (§ 417.101(a)(2));

(3) Medically necessary emergency health services (§ 417.101(a)(3)); and

(4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§ 417.101(a)(6)).

"Direct service contract" means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

"Full-time student" means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

"HCFA" stands for Health Care Financing Administration.

"Health maintenance organization" (HMO) means a legal entity which provides or arranges for the provision of basic and supplemental health services to its members in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the Public Health Service Act and the regulations of §§ 417.100 through 417.109.

"Health professionals" means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, social workers, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

"Individual practice association" (IPA) means a partnership, association, corporation, or other legal entity which delivers or arranges for the delivery of health services and which has entered into written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement shall provide:

(1) That these health professionals shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(2) To the extent feasible, for the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff.

"Medical group" means a partnership, association, corporation, or other group:

(1) Which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services or which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) After the end of the 48 month period beginning after the month in which the HMO for which the group provides health services becomes a qualified HMO, as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

"Medical group members" means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

"Medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services. The Secretary will designate these areas as described in § 417.112(d).

"Member," when used in connection with an HMO, means an individual who has entered into a contractual relationship with the HMO or on whose behalf a contractual arrangement has been entered into with the HMO by a subscriber under which the HMO assumes the responsibility for the provision to the member of basic health services and such supplemental health services as may be contracted for.

"Nonmetropolitan area" means an area no part of which is within a standard metropolitan statistical area as designated by the Office of Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

"Party in interest" means: (1) Any director, officer, partner, or employee responsible for management or administration of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

(2) Any entity in which a person described in paragraph (1):

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any spouse, child, or parent of an individual described in paragraph (1).

"Policymaking body" of an HMO means a board of directors, governing body, or other body of individuals which has the authority to establish policy for the HMO.

"Qualified HMO" means an HMO found by the Secretary to be qualified within the meaning of section 1310 of the Public Health Service Act and §§ 417.140 through 417.144 of this subpart.

"Rural area" means any area not listed as a place having a population of 2,500 or more in Document #PC(1)A, "Number of Inhabitants," Table VI, "Population of Places," and not listed as an urbanized area in Table XI, "Population of Urbanized Areas" of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Service area" means the geographic area as defined through zip codes, census tracts, or other geographic subdivisions, found by the Secretary to be the area within which the HMO provides or arranges for basic and supplemental health services that are available and accessible to its members as required by section 1301(b)(4) of the Public Health Service Act.

"Significant business transaction" means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of $25,000 or 5 percent of the total operating expenses of the HMO.

"Staff of the HMO" means health professionals who are employees of the HMO and who:

(1) Provide services to HMO members at an HMO facility subject to the staff policies and operational procedures of the HMO;

(2) Engage in the coordinated practice of their profession and provide to members of the HMO the health services which the HMO has contracted to provide;

(3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO;

(4) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

"Subscriber" means a member who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

"Supplemental health services" means the health services described in § 417.102(a).

"Unusual or infrequently used health services" means: (1) Those health services which are projected to involve fewer than 1 percent of the encounters per year for the entire HMO membership, or,

(2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19338, May 5, 1982; 52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.101 Health benefits plan: Basic health services.

(a) An HMO shall provide or arrange for the provision of basic health services to its members as needed and without limitations as to time and cost other than those prescribed in the Public Health Service Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which shall be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which shall include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital; (ii) inpatient hospital services, which shall include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma; (iii) outpatient services and inpatient hospital services shall include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its members on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per member per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs shall include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services shall be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

(8) Preventive health services, which shall be made available to members and shall include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in § 417.102 as a supplemental health service in the basic health services which it provides or arranges for its members for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of §§ 417.100 through 417.109, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the Public Health Service Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the member is legally entitled to services and for which facilities are reasonably available to this member;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the Public Health Service Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgi-

cal beds, respirators, dialysis machines); and

(16) Health services which are unusual and infrequently provided and not necessary for the protection of individual health, as approved by the Secretary upon application by the HMO.

(e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis which do not include all the basic health services set forth in paragraph (a) of this section or which are limited as to time and cost except in a manner prescribed by this subpart.

§ 417.102 Health benefits plan: Supplemental health services.

(a) An HMO may provide to its members any health service which is not included as a basic health service under § 417.101(a). These health services may be limited as to time and cost.

(b) An HMO shall determine the level and scope of supplemental health services included with basic health services provided to its members for a basic health services payment or those services offered to its members as supplemental health services.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.103 Providers of basic and supplemental health services.

(a)(1) The HMO shall provide that the services of health professionals which are provided as basic health services will, except as provided in paragraph (c) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, the Secretary approves the sharing as being consistent with the purposes of section 1310(b) of the Public Health Service Act.

(3) After the 4 year period beginning with the month following the month in which an HMO becomes a qualified HMO, an entity which meets the requirements of the definition of medical group in § 417.100, except for subdivision (3)(i) of that definition, may be considered a medical group if the Secretrary determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of the Secretary that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(i) Presenting a reasonable time-phased plan for the entity to achieve compliance with the "substantial responsibility" requirement of subdivision (3)(i) of the definition of "medical group" in § 417.100. The HMO shall update the plan annually and shall demonstrate to the satisfaction of the Secretary that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of "medical group," or

(ii) Demonstrating that compliance by the entity with the "substantial responsibility" requirement is unreasonable or impractical because (A) the HMO serves a non-metropolitan or rural area as defined in § 417.100, or (B) the entity is a multi-speciality group which provides medical consultation upon referral on a regional or national basis, or (C) the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of members to require utilization of at least 35 percent of the entity's services.

(b) HMOs shall have effective procedures to monitor utilization and to control cost of basic and supplemental health services and to achieve utilization goals, which may include mechanisms such as risk sharing, financial incentives, or other provisions agreed to by providers.

(c) Paragraph (a) of this section does not apply to the provision of the services of a physician:

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the member other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as community mental health centers, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(d) Supplemental health services shall be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(e) Each HMO shall:

(1) Pay the provider, or reimburse its members for the payment of reasonable charges for basic health services (or supplemental health services which the HMO agreed to provide on a prepayment basis) for which its members have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from members for reimbursement for the provision of health services described in paragraph (e)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its members on procedures to be followed to secure these health services.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17))

[45 FR 72528, Oct. 31, 1980; 45 FR 77031, Nov. 21, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6174, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.104 Payment for basic health services.

(a) *Basic health services payment.* Each HMO shall provide or arrange for the provision of basic health services for a basic health services payment which:

(1) Is to be paid on a periodic basis without regard to the dates these services are provided;

(2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;

(3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and

(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.

(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its members, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.

(ii) To insure that copayments are not a barrier to the utilization of health services or membership in the HMO, an HMO may not impose copayment charges on any subscriber (or members covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or members) in that calendar year total 200 percent of the total annual premium cost which that subscriber (or members) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or members) demonstrates that copayments in that amount have been paid in that year.

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per person or per family basis, as described in paragraph (b)(1) of this section or on a per group basis as described in paragraph (b)(2) of this section. An HMO may fix its rates of payment under the system described in paragraph (b)(1) or (b)(2) of this section or under both such systems, but an HMO may use only one such system for fixing its rates of payment for any one group.

(1) A system of fixing rates of payment for health services may provide that the rates shall be fixed on a per person or per family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group is substantially equivalent to the revenue which would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers shall be calculated to yield revenues substantially equivalent to the product of the total number of members (or subscribers) expected to be enrolled from the group and the per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. Under the system described in this paragraph, rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment which are established for new enrollments or re-enrollments and which do not apply to existing contracts until the renewal of these contracts.

(2) A system of fixing rates of payment for health services may provide that the rates shall be fixed for individuals and families by groups. Except as otherwise authorized in this paragraph, such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If an HMO is to fix rates of payment for individuals and families by groups, it shall:

(i) Classify all of the members of the organization into classes based on factors which the HMO determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary,

(ii) Determine its revenue requirements for providing services to the members of each class established under paragraph (b)(2)(i) of this section, and

(iii) Fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under paragraph (b)(2)(ii) of this section for providing services to them as members of the classes established under paragraph (b)(2)(i) of this section. The Secretary will review the factors used by each HMO to establish classes under paragraph (b)(2)(i) of this section. If the Secretary determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, the Secretary will disapprove the factor for that purpose.

(3)(i) Nominal differentials in rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of potential subscribers:

(A) Individual (non-group) subscribers (including their families).

(B) Small groups of subscribers (100 subscribers or fewer).

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in an HMO: (A) Under a contract with a governmental authority under section 1079 ("Contracts for Medical Care for Spouses and Children: Plans") or section 1086 ("Contracts for Health Benefits for Certain Members, Former Members and their Dependents") of Title 10 ("Armed Forces"), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 ("Health Insurance") of Title 5 ("Government Organization and Employees"), United States Code; or (C) under any health benefits program for employees of States, political subdivisions of states, and other public entities.

(4) An HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to the Secretary of the following:

(i) Each regional component is geographically distinct and separate from any other regional component; and

(ii) Each regional component provides substantially the full range of basic health services to its members, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement.* (1) In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided a member who is a full-time student at an accredited institution of higher education.

(d) *Late payment penalty.* HMOs may charge a late payment penalty on accounts receivable which are in arrears.

(e) *Review procedures for evaluating the community rating by class system under paragraph (b)(2).*[1] An HMO may establish a community rating system under paragraph (b)(2) of this section or revised factors used to establish classes after it receives written approval of the factors from the Secretary. The Secretary will give approval if he or she concludes that the factors can reasonably be used to predict the use of health services by individuals and families.

(1) An HMO must make a written request to the Secretary, listing the factors to be used in the community rating by class system under paragraph (b)(2) of this section.

(2) The Secretary will notify each HMO within 30 days of receipt of the request and application of one of the following:

(i) The application is approved;

(ii) Additional information or data are required and the Secretary will notify the HMO of his or her decision within 30 days from the date of receipt of this information or data; or

(iii) The Secretary needs additional time to review the written request and the HMO will be notified of the Secretary's decision within 90 days.

(Approved by the Office of Management and Budget under control number 0915-0051)

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17)

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.105 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in § 417.102 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its members for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-service. Supplemental health services payments which are fixed on a prepayment basis, however, shall be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student at an accredited institution of higher education. In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

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[1] Further information entitled "Guidelines for Rating by Class" may be obtained by requesting it from the Associate Director for Health Maintenance Organizations, Parklawn Building, Rm. 9-05, 5600 Fishers Lane, Rockville, Maryland 20857.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17)

[45 FR 72528, Oct. 31, 1980, as amended at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.106 Availability, accessibility, and continuity of basic and supplemental health services.

Within the HMO's service area, basic health services and those supplemental health services for which members have contracted shall be:

(a) Provided or arranged for by the HMO;

(b) Available and accessible to each of the HMO's members with reasonable promptness with respect to:

(1) Geographic location, hours of operation, and provisions for after-hours services (medically necessary emergency services must be available and accessible 24 hours a day, 7 days a week), except that an HMO which has a service area located wholly in a non-metropolitan area may make a basic health service available outside its service area if that basic health service is not a primary care or emergency care service and if there is an insufficient number of providers of that basic health service within the service area who will provide that service to members of the HMO. For purposes of this paragraph, the term primary care includes the fields of general practice, family practice, general internal medicine, general pediatrics, and general obstetrics and gynecology. An HMO providing the services that are covered by these fields through at least (i) a general or family practitioner, or (ii) a pediatrician and a general internist, would be viewed as providing primary care; and

(2) Staffing patterns within generally accepted norms for meeting the projected membership needs; and

(c) Provided in a manner which assures continuity, including but not limited to:

(1) Provision of a health professional who is primarily responsible for coordinating the member's overall health care; and

(2) Development of a health (including medical) recordkeeping system through which pertinent information relating to the health care of the patient is accumulated and is readily available to appropriate professionals.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17)

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19340, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.107 Organization and operation.

(a) *Fiscally sound operation and administrative and managerial arrangements.* (1) Each HMO shall have a fiscally sound operation as demonstrated by:

(i) Total assets being greater than total unsubordinated liabilities. In this evaluation, loan funds awarded or guaranteed under section 1305 of the Public Health Service Act are not included as liabilities, and if the funds have not been disbursed to the HMO by the Secretary or by an escrow agent, they are not included as assets;

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due;

(iii) A net operating surplus. If the HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year, does not a have positive net worth, or is seeking a Federal loan or loan guarantee under sections 1305 or 1305A of the Public Health Service Act, the HMO shall submit a financial plan satisfactory to the Secretary to achieve net operating surplus within available fiscal resources. This plan shall include:

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds' statements; and

(D) Balance sheets;

(iv) A plan for handling insolvency which allows for continuation of benefits for the duration of the contract period for which payment has been made and continuation of benefits to members who are confined on the date of insolvency in an inpatient facility until their discharge.

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO;

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by the Secretary to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks; and

(2) Each HMO shall have administrative and mangerial arrangements satisfactory to the Secretary, as demonstrated by at least the following:

(i) A policymaking body which exercises oversight and control over the HMO's policies and personnel to assure that management actions are in the best interest of the HMO and its membership; and

(ii) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO. At a minimum, the HMO shall be managed by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(3) *Protection of members.* (i) Each HMO shall adopt and maintain arrangements satisfactory to the Secretary to protect its members from incurring liability for payment of any fees which are the legal obligation of the HMO. These arrangements may include:

(A) Contractual arrangements with health care providers used by the members of the HMO prohibiting the providers from holding any member liable for payment of any fees which are the legal obligation of the HMO;

(B) Insurance, acceptable to the Secretary;

(C) Financial reserves, acceptable to the Secretary, that are held for the HMO and restricted for use only in the event of insolvency; or

(D) Any other arrangements acceptable to the Secretary.

(ii) The requirements of this paragraph do not apply to an HMO if the Secretary determines that applicable State law provides that members of the HMO may not be liable for payment of any fees which are the legal obligation of the HMO.

(b) *Financial risk.* Each HMO shall assume full financial risk on a prospective basis for the provisions of basic health services, except that it may (1) Obtain insurance or make other arrangements for the cost of providing to any member basic health services the aggregate value of which exceeds $5,000 in any year;

(2) Obtain insurance or make other arrangements for the cost of basic health services provided to its members other than through the HMO because medical necessity required their provision before they could be secured through the HMO;

(3) Obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year; and

(4) Make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(c)(1) *Full and fair disclosure.* Each HMO shall prepare a written description of the items listed below. This description shall be written so that it can be easily understood by the average person who might enroll in the HMO. The description of benefits and coverage (items in paragraph (c)(1) (i) and (ii) of this section, respectively, below) may be in general terms if reference is made to a detailed statement of benefits and coverage which is available without cost to any person to whom the opportunity for enrollment in the HMO is offered or who has enrolled in the HMO. Upon request made directly to the HMO or the plan administrator (as that term is defined under the Employee Retirement Income Security Act of 1974, "ERISA") of a health benefits plan which includes the HMO option, the HMO shall provide the description to any person who is a participant or beneficiary of the plan and who is eligible to elect the HMO option. The items to be included in the written description are the HMO's:

(i) Benefits (including limitations and exclusions);

(ii) Coverage (including a statement of conditions on eligibility for benefits);

(iii) Procedures to be followed in obtaining benefits and a description of circumstances under which benefits may be denied;

(iv) Rates;

(v) Grievance procedures;

(vi) Service area;

(vii) Participating providers:

(A) If the HMO provides health services through an individual practice association(s), the HMO shall provide the number of member physicians by specialty, and a listing of the hospitals where HMO members will receive basic and supplemental health services; and

(B) If the HMO provides health services other than through an individual practice association, the HMO shall provide for each ambulatory care facility, the facility's address, days and hours of operation, and the number of physicians by specialty, and a listing of the hospitals where HMO members will receive basic and supplemental health services; and

(viii) Financial condition to include at least the following most recently audited information: Current assets, other assets, total assets; current liabilities, long term liabilities; and net worth.

(2) *Broadly representative enrollment.* After providing the written description referred to in paragraph (c)(1) of this section, each HMO shall offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area. In the case of an HMO which has a medically underserved population located in its service area, not more than 75 percent of the HMO members may be enrolled from the medically underserved population unless the area in which that population resides is also a rural area.

(d) *Health status and enrollment.* The HMO shall not expel or refuse to re-enroll any member nor refuse to enroll individual members of a group, on the basis of the health status, health care needs, or age of the member or individual. For purposes of this paragraph, a "group" is an entity which consists of members who enroll in the HMO through a contract or other arrangement which provides for the enrollment of two or more subscribers. Nothing in §§ 417.100 through 417.109 prohibits an HMO from requiring that, as a condition of continued eligibility for membership, dependents of a subscriber, upon reaching a specified age, convert to nongroup membership consistent with the terms of § 417.107(g).

(e) *Conversion of membership.* Each HMO shall offer membership on the same terms and conditions as are available to a nongroup subscriber to:

(1) Each subscriber (and his enrolled dependents) leaving a group; and

(2) Each member who would otherwise cease to be eligible for HMO membership because of his or her age or the death or divorce of a subscriber.

(f) *Policymaking body.* (1) In the case of a private HMO, no later than one year after becoming operational as a qualified HMO, at least one-third of the membership of its policymaking body must be members of the HMO who reside in or in proximity to the service area of the HMO. An HMO with regional components and one overall policymaking body must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMO's regional components. HMOs with policymaking bodies consisting of the same individuals must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMOs.

(i) No member having ownership of or financial interest in, or employed by, or gaining financial reward from direct dealings with, the HMO or a plan-affiliated institution or organization, and no members of the immediate family of such member shall be included in the minimum one-third representation on the policymaking body. However, none of the foregoing prohibits the payments of directors' fees or other similar fees, or interest and dividends derived from membership in an HMO cooperative, to persons serving on the policymaking body. Any person who is not directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO or a plan-affiliated institution or organization is deemed not to have ownership of or financial interest in the HMO or the plan-affiliated institution or organization.

(ii) There shall be equitable representation on the member portion of the policymaking body of members from the medically underserved populations served by the HMO in proportion to their enrollment relative to the entire enrollment.

(2) In the case of public HMO, have an advisory board to its policymaking body operating the HMO which board meets the requirements of paragraph (f)(1) of this section, and to which may be delegated policymaking authority for the HMO.

(g) *Grievance procedures.* Each HMO shall have and use meaningful procedures for hearing and resolving grievances between the HMO (including the staff of the HMO, the medical group, and the IPA) and the members of the HMO. These procedures must assure that: (1) Grievances and complaints will be transmitted in a timely manner to appropriate decisionmaking levels within the HMO which have authority to take corrective action; and (2) appropriate action will be taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

(h) *Quality assurance program.* Each HMO shall have an ongoing quality assurance program for is health services which:

(1) Stresses health outcomes to the extent consistent with the state of the art;

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services;

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change; and

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services which should have been furnished have not been provided;

(i) *Certification of institutional providers.* Each HMO shall assure that institutional providers through which it provides basic and supplemental health services (1) are certified either under Title XVIII of the Social Security Act (Medicare) in accordance with 42 CFR Part 405 or under Title XIX of the Social Security Act (Medicaid) in accordance with the regulations governing participation of providers in the Medical Assistance Program; or (2) in the case of hospitals, are either accredited by the Joint Commission on Accreditation of Hospitals or certified by Medicare; or (3) in the case of clinical laboratories (except for laboratories exempted from section 353 of the Public Health Service Act by paragraph (d)(2), (i), or (l) of that section), certified by Medicare or Medicaid or licensed under section 353.

(j) *Reporting and disclosure requirements.* (1) While safeguarding the confidentiality of the doctor-patient relationship, each HMO shall provide an effective procedure to develop, compile, evaluate, and report to the Secretary, to its members, and to the general public, at the times and in the manner the Secretary requires, statistics and other information relating to:

(i) The cost of its operations;

(ii) The patterns of utilization of its services;

(iii) The availability, accessibility, and acceptability of its services;

(iv) To the extent practical, developments in the health status of its members;

(v) Information demonstrating that the HMO has a fiscally sound operation;

(vi) Other matters as the Secretary may require.

(2) Each HMO shall report to the Secretary annually, within 180 days of the end of its fiscal year (unless for good cause shown, the Secretary authorizes an extension of time):

(i) A copy of the report, if any, filed with the Department's Health Care Financing Administration containing the information required to be reported by disclosing entities under regulations implementing section 1124 and section 1902(a)(38) of the Social Security Act (see 42 CFR 420.206 and 42 CFR 455.104), respectively; and

(ii) A description of the following significant business transactions between the HMO and a party in interest, and a justification that the costs of these transactions do not exceed the costs which would be incurred if these transactions were to be with someone who is not a party in interest (or if they do, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements):

(A) Sale, exchange, or leasing of property;

(B) Furnishing for consideration of goods, services (including management services), or facilities between the HMO and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical groups, IPAs, or any combination thereof; and

(C) Lending of money and other extension of credit.

(3)(i) Report to the Secretary annually, within 180 days of the end of its fiscal year (unless for good cause shown, the Secretary authorizes an extension of time), a combined financial statement for the organization and such entity if:

(A) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest; or

(B) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

The combined financial statements must display in separate columns the financial information for the HMO and each of these parties in interest. Inter-entity transactions must be eliminated in the consolidated column. These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(ii) The Secretary may, upon a written request from an HMO and for good cause shown, waive the requirement that its combined financial statement include the financial information required in this paragraph with respect to a particular entity.

(k) *Confidentiality of health records.* Each HMO shall establish adequate procedures to insure confidentiality of its members' health (including medical) records; and

(l) *Referral information.* Each HMO shall make arrangements either directly or through its providers to assure that the HMO or the health professional coordinating the member's overall health care is kept informed about the services provided to its members by referral resources.

(m) *Reporting and Disclosure under ERISA.* Each HMO shall provide each employer or designee (as those terms are defined in § 417.150 of this subpart) or plan administrator (as that term is defined under the Employee Retirement Income Security Act of 1974, "ERISA") including the HMO option in its employees' health benefits plan, upon request, the information which is necessary to satisfy its reporting and disclosure obligations under ERISA insofar as that HMO is involved.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17)

[45 FR 72528, Oct. 31, 1980, as amended at 46 FR 6355, Jan. 21, 1981; 47 FR 19340, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.108 Special requirements: Titles XVIII and XIX of the Social Security Act.

(a) As provided in section 1307(d) of the Public Health Service Act, an HMO which otherwise complies with section 1301(b) and section 1301(c) of the Public Health Service Act, and with the applicable regulations of §§ 417.100 through 417.109, and which enrolls members who are entitled to insurance benefits under Title XVIII of the Social Security Act or to medical assistance under a State plan approved under Title XIX of that Act, may still be considered as an HMO, if with respect to its Title XVIII and Title XIX members it provides services and is operated as required by Title XVIII or XIX, as appropriate, and regulations thereunder.

(b) Notwithstanding any inconsistent requirements of §§ 417.100 through 417.109, an HMO which enters into a contract with the Secretary under Title XVIII of the Social Security Act or with a State under Title XIX of that Act shall, with respect to its members entitled to insurance benefits or medical assistance under those titles, comply with the applicable Title XVIII or Title XIX requirements, including deductible and coinsurance requirements, enrollment mix and enrollment practice requirements, in accordance with the provisions of Title XVIII or the Title XIX State plan of the State with which it is contracting. Copayment options which are not in accordance with a Title XIX State plan may not be imposed on Title XIX enrollees.

(c) Any grievance procedures authorized under Title XVIII or Title XIX of the Social Security Act are not superseded by the provisions of § 417.107(i).

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17)

[45 FR 72528, Oct. 31, 1980. Redesignated at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.109 Special requirements: Federal employee health benefits program.

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by Chapter 89 of Title 5, United States Code, may be considered as an HMO for purposes of receiving assistance under this subpart if with respect to its other members it (a) provides health services in accordance with section 1301(b) of the Public Health Service Act and the applicable regulations of this subpart and (b) is organized and operated in the manner prescribed by section 1301(c) of the Public Health Service Act and the applicable regulations of this subpart.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17)

[45 FR 72528, Oct. 31, 1980. Redesignated at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

FEDERAL FINANCIAL ASSISTANCE: GENERAL

SOURCE: 44 FR 42076, July 18, 1979, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.110 To whom do these regulations apply?

The regulations of §§ 417.110 through 417.119 apply to the award of grants, loans, and loan guarantees to public or private entities for projects as authorized by sections 1303, 1304, 1305, and 1305A of the Public Health Service Act.

§ 417.111 Definitions.

"Expansion of services" means (1) the addition of any health service not previously provided by or through the HMO, which requires an increase in the facilities, equipment, or health professionals of the HMO, or (2) the improvement or upgrading of existing facilities or equipment, or an increase in the number or categories of health professionals, of the HMO so that the HMO may provide directly services which it previously provided through contract or referral or which it could not previously provide with its existing facilities or equipment.

"Health system agency" means an entity which has been designated in accordance with section 1515 of the Public Health Service Act; and the term "State Health planning and development agency" means an agency which has been designated in accordance with section 1521 of the Public Health Service Act.

"Nonprofit" as applied to a private entity, agency, institution, or organization means a private entity, agency, institution, or organization, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"Significant expansion" means (1) a planned substantial increase in membership of the HMO which will require an increase in the number of health professionals serving members of the HMO or an expansion of the physical capacity of the HMO's total health facilities; or (2) a planned expansion of the service area beyond the current service area which would be made possible by the addition of health service delivery facilities and health professionals to serve members at a new site or sites in areas previously without service sites. Only organizations which have been found by the Secretary to be qualified HMOs are eligible to apply for assistance for expansion under sections 1303 and 1304 of the Public Health Service Act.

§ 417.112 What are the requirements for an application?

(a) *Financial information.* On the basis of the information submitted by the applicant, the Secretary will determine whether the applicant would not be able to complete the project without the assistance for which it has applied.

(b) *Assurances.* Each application must contain the following assurances, as appropriate, which are binding on successors, assignees, and transferees of the applicant, as well as the applicant:

(1) In the case of an application for assistance under section 1303 of the Public Health Service Act, if the survey or other activity supported demonstrates that the development and operation or the expansion of the operation of an HMO is feasible, the applicant will be, or will form, or expand the operation of, as appropriate, and HMO;

(2) In the case of an application for assistance under section 1304 of the Public Health Service Act, the applicant will develop and operate or expand the operation of, as the case may be, an HMO;

(3) When operational as an HMO, the applicant will (i) provide basic health services to its members, (ii) provide these services in the manner prescribed by section 1301(b) of the Public Health Service Act and by the regulations of this subpart, and (iii) be organized and operated in the manner prescribed by section 1301(c) of the Public Health Service Act and by the regulations of this subpart;

(4) When operational as an HMO, the applicant will enroll, and maintain an enrollment of, the maximum number of members that is available and potential resources will enable it to serve effectively. Maximum number of members is defined as the actual or projected enrollment which the HMO can serve, considering the availability of the required health manpower in the area to be served by the organization and the capacity of the facilities of the organization;

(5) A statement of intent (including evidence of the applicant's ability) to meet the requirements of paragraphs (1) and (2) of section 1301(b) of the Public Health Service Act and the applicable regulations of this subpart respecting the fixing of payments for basic health services and supplemental health services for which the member has contracted on a prepayment basis under a community rating system; and

(6) In the case of an application for assistance under sections 1304 and 1305 of the Public Health Service Act filed by a nonprofit entity, the applicant will become a nonprofit HMO, will maintain its nonprofit status

unless for good cause shown the Secretary releases the applicant from this assurance, and will upon a change in its nonprofit status notify the Secretary immediately.

(c) *Nonmetropolitan areas.* Each application which evidences or projects an enrollment of at least 66 percent from a nonmetropolitan area shall identify the area and indicate the percent of anticipated enrollment to be drawn from that area.

(d) *Medically underserved areas.* Each application which evidences or projects an enrollment of at least 30 percent of its members from a medically underserved population when the HMO first receives financial assistance or becomes operational shall identify the area in which that population resides, the total population of that area, and the percent of anticipated enrollment to be drawn from the medically underserved area. Medically underserved areas are designated by the Secretary taking into consideration at least the following factors:

(1) Ratio of primary care physicians to population;

(2) Infant mortality rate;

(3) Percentage of the population which is age 65 or over; and

(4) Percentage of the population with family income below the poverty level.

The Secretary will designate these areas only after consideration of the comments, if any, of the appropriate health systems agency or State health planning and development agency whose plan covers any part of the area in which the population group resides.[1]

(e) *Health planning agency reviews.* Each applicant must show in its application that it has sent to each health systems agency whose health service area covers any part of the area to be served by the HMO for which the application is submitted (or if there is no such agency, the State health planning and development agency whose State includes any part of the area to be served) a copy of the application. The agency may then review and comment on the application in accordance with § 417.113.

(f) *Health planning agency approvals.* If applicable State law provides that the application may not be submitted without the approval of the health systems agency, or State health planning and development agency, the applicant shall obtain this approval which must be included as a part of the application.

(g) *Other projects under the Public Health Service Act.* The application shall provide written information describing the applicant's development and operation of any prior projects which were supported by grants or by loans or loan guarantees under Title XIII of the Public Health Service Act. Applicants must also describe projects for the planning or operation of health service delivery programs supported under any other titles of the Public Health Service Act, or for which applications under the Public Health Service Act are currently under consideration.

(h) *Other applications under Title XIII of the Public Health Service Act.* Applicants for more than one grant, loan, or loan guarantee under Title XIII of the Public Health Service Act, simultaneously or over the course of time, are not required to submit duplicate information, but shall indicate where the information was previously contained and shall update appropriate information with each subsequent application. Upon receiving a written request, the HMO shall submit to the appropriate planning agency referred to in paragragph (e) any previous applications for grants, loans, or loan quarantees under Title XIII of the Public Health Service Act not already submitted to that agency.

[44 FR 42076, July 18, 1979, as amended at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

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[1] A list of medically underserved areas already designated may be obtained by writing the Regional Health Administrator in the appropriate Regional Office of the Department of Health and Human Services at the addresses set forth at 45 CFR 5.31(b).

§ 417.113 What are the standards and procedures for review and comment by the appropriate health systems agency or State health planning and development agency?

(a) *Time, manner and considerations for review and comment.* If the appropriate health systems agency or State health planning and development agency elects to review and comment upon the application, it shall within 67 days after receiving an application for financial assistance under this subpart provide to the Secretary comments and recommendations regarding the application. Except as provided in paragraph (c) of this section, the agency shall base its review and comment solely on the following considerations:

(1) The needs of enrolled members and reasonably anticipated new members of the HMO or proposed HMO applying for assistance for the health services proposed to be provided by the organization.

(2) The availability of the proposed health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO or proposed HMO applying for assistance. In assessing the availability of health services from these providers, the agency shall consider only whether the services from these providers:

(i) Would be available under a contract of at least five years duration;

(ii) Would be available and conveniently accessible through physicians and other health professionals associated with the HMO or proposed HMO (for example: Whether physicians associated with the HMO have or will have full staff privileges at a non-HMO hospital);

(iii) Would cost no more than if the services were provided by the HMO or proposed HMO; and

(iv) Would be available in a manner which is administratively feasible to the HMO or proposed HMO.

(b) *Inappropriate considerations for review and comment.* (1) The health systems agency or State health planning and development agency should not recommend against approval of an application solely because there is an HMO of the same type, as specified in section 1310(b) of the Public Health Service Act, in the same area, or solely because the services being reviewed are not discussed in the applicable health systems plan, annual implementation plan, State health plan, or State medical facilities plan.

(2) The health systems agency or State health planning and development agency should not recommend against approval of an application for financial assistance for planning or initial development or initial operating costs under §§ 417.120 through 417.126 and 417.130 through 417.137, which is consistent with the basic objectives, time schedules, and plans of an application which it previously approved or recommended for approval.

(c) *Additional considerations for review and comment.* A health systems agency or State health planning and development agency may propose to the Secretary that it be permitted to base its reviews and comments on additional considerations not set forth in paragraph (a) of this section. Any agency making such a request for permission to use additional considerations shall do so in writing, specifying the reasons for the proposal, and shall send a copy of the request to any applicants for financial assistance under this subpart whose applications are then being reviewed by the agency. No pending reviews may be delayed because the agency has submitted such a request to the Secretary. The Secretary will approve the request if he finds the additional considerations to be consistent with the purpose of Title XIII of the Public Health Service Act. Unless the Secretary has approved the use of the additional considerations, the agency shall base its reviews and comments solely on the considerations set forth in paragraph (a) of this section.

[44 FR 42076, July 18, 1979, as amended at 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.114 What additional conditions may the Secretary impose?

(a) The Secretary may, with respect to the approval of any grant, contract, loan, or loan guarantee, impose additional conditions prior to or at the time of any approval when, in his judgment, these conditions are necessary to assure or protect the advancement of the approved project, the interests of public health, or the conservation of project funds.

(b) In approving any application under section 1303 or 1304 of the Public Health Service Act for feasibility, planning, or initial development, the Secretary may reserve the right to approve the project director.

[44 FR 42076, July 18, 1979. Redesignated and amended at 45 FR 55122, Aug. 18, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.115 What confidentiality requirements apply?

(a) Except as set forth in paragraph (b) of this section, each recipient of assistance under this subpart shall hold confidential all information obtained by its personnel about participants in the project related to their examination, care, and treatment and shall not divulge it without the individual's authorization, unless it is required by law or is necessary to provided service to the individual or in compelling circumstances to protect the health or safety of an individual.

(b) Information may be disclosed in summary, statistical, or other form which does not identify particular individuals. Information may be disclosed, whether or not authorized by the participants, to the Secretary or the Comptroller General if it is necessary for the performance of their duties under the Public Health Service Act. Records pertaining to project participants may be disclosed, whether or not authorized by the participants, to qualified personnel for the purpose of conducting scientific research, but these personnel may not identify, directly or indirectly, any individual participant in any report of the research or otherwise disclose participant identities in any manner.

(c) Separate HHS regulations at 42 CFR Part 2, set forth standards for maintaining the confidentiality of alcohol and drug abuse patient records. Under § 2.12 of the regulations, the applicability of these requirements extends, for example, to all HMOs which have received a loan from the Secretary under section 1305 of the Public Health Service Act or which have been granted a tax exempt status by the United States Internal Revenue Service. To the extent that an HMO subject to Part 2 would be authorized under paragraph (b) of this section to make a disclosure prohibited by Part 2, the provisions of Part 2 would control.

[44 FR 42076, July 18, 1979. Redesignated at 45 FR 55122 and 55123, Aug. 18, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.116 For what purposes may grant funds be used?

A grantee may spend funds it receives under this subpart only according to the approved application and budget, Title XIII of the Public Health Service Act, the terms and conditions of the grant award, the applicable cost principles specified in Subpart Q of 45 CFR Part 74, and the regulations of this subpart.

[45 FR 55123, Aug. 18, 80. Redesignated at 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.117 What is the effect of a grantee's failure to become or to remain a qualified HMO?

The failure of a grantee to become a qualified HMO in accordance with §§ 417.140 through 417.144 of this subpart, or to remain a qualified HMO, is a material failure to comply with the terms of the grant. Upon this failure, the subsequent use and disposition of any property acquired with grant funds will be governed by 45 CFR Part 74.

(a) If the grant project period has not yet expired, this failure is grounds for termination of the grant under 45 CFR Part 74.115(a).

(b) If the grant period has expired, property acquired with grant funds will be deemed, under 45 CFR Part 74, Subpart O, to be no longer needed for the program or project for which it was acquired.

[45 FR 55123, Aug. 18, 1980. Redesignated at 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.118 What obligation does the Federal Government have to continue support for an approved project?

(a) The notice of award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. For feasibility grants under and planning grants and loan guarantees under §§ 417.120 through 417.126, this period, called the project period, will usually be for, and cannot exceed, one year. For initial development grants and loan guarantees under §§ 417.120 through 417.126, the project period will usually be for 1-3 years and cannot exceed three years.

(b) Generally, the initial development grant or loan guarantee will be for one year initially and subsequent continuation awards will also generally be for one year at a time. Although the project period for a feasibility grant and for a planning grant or loan guarantee is limited to one year, the Secretary may either make one additional grant or loan guarantee for such a project or permit additional time (up to one year) for completion of the project. A grantee or a recipient of a loan guarantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the assistance level of such awards will be made after consideration of such factors as the progress and management practices of the grantee or recipient of the loan guarantee, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued assistance is in the best interest of the Federal government.

(c) Neither the approval of any application nor the making of an award commits or obligates the Federal government in any way to make an additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

[45 FR 55123, Aug. 1, 1980. Redesignated at 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.119 What is the effect of a grantee's change from non-profit to for-profit status?

(a) Any non-profit private entity which received a grant under section 1304 of the Public Health Service Act and which becomes a for-profit private entity, shall notify the Secretary of this change of status within 30 days of the change.

(b) Any grantee which becomes a for-profit entity after receiving a grant under section 1304 of the Public Health Service Act shall immediately upon demand by the Secretary repay to the Secretary the total amount of grant funds received under section 1304, unless the Secretary determines for good cause that waiver of all or part of this amount would be in the interest of the United States. This sum constitutes a debt owed by the grantee to the Federal Government, and the Government may recover it from the grantee or its successors or assignees by setoff or other action as provided by law.

[44 FR 42076, July 18, 1979. Redesignated at 45 FR 55123, Aug. 1, 1980, and amended at 47 FR 19340, May 5, 1982. Redesignated at 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

Grants and Loan Guarantees for Planning and Initial Development Costs

Source: 43 FR 6023, Feb. 10, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.120 Applicability.

(a) The regulations of §§ 417.120 through 417.126, in addition to the regulations of §§ 417.110 through 417.119 of this subpart, apply to:

(1) Grants awarded under section 1304 of the Public Health Service Act for projects for the planning and for the initial development of HMOs.

(2) Guarantees made under section 1304 of the Public Health Service Act to non-Federal lenders of payment of the principal of and the interest on loans made for projects for the planning and initial development of HMOs.

(b)(1) Planning projects include projects for (i) the establishment of an

HMO, and (ii) the significant expansion (as defined in § 417.111) of the membership or of the area served by an HMO.

(2) Initial development projects include projects for (i) the establishment of an HMO, (ii) the significant expansion (as defined in § 417.111) of the membership or of the area served by an HMO, and (iii) the expansion of the services (as defined in § 417.111) of an HMO.

[45 FR 6059, Jan. 24, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.121 Eligible applicants.

Any public entity or nonprofit private entity which is, or which proposes to become, an HMO and which received a grant or contract under section 1303 or section 1304 of the Public Health Service Act on or before September 30, 1981 is eligible to apply for a grant or a loan guarantee under §§ 417.120 through 417.126. A for-profit private entity which is, or which proposes to become, an HMO is only eligible to apply for a loan guarantee under this §§ 417.120 through 417.126.

(a) In the case of a for-profit private entity, the applicant must demonstrate that at least 10 percent of the projected membership of the HMO to be established or expanded will be from medically underserved populations.

(b) Only HMOs qualified under §§ 417.140 through 417.144 of this subpart are eligible to apply for projects for the significant expansion of their membership or of their service areas or for the expansion of their services.

[45 FR 6059, Jan. 24, 1980, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.122 Project elements for planning.

An approvable application must provide:

(a) Statements which describe in detail:

(1) The goals and objectives of the proposed health maintenance organization;

(2) The administrative, managerial, and organizational arrangements;

(3) The resources to be used including consultants whose tasks must be defined adequately to permit an evaluation of the need for such consultants;

(4) The existing or proposed composition of the Board of Directors of the applicant organization and its duties;

(5) The proposed service area and the surrounding community, the number of employed persons and number of primary care physicians located in the proposed service area; and

(6) The intended financial participation of the applicant, specifying the type of contribution such as cash or services, loans of full- or part-time staff, equipment, space, materials, facilities, or other contributions.

(b) An assurance that the applicant will cooperate with the appropriate health systems agency and State health planning and development agency.

(c) Written evidence of notification to the local medical society or societies of the applicant's intention to apply for assistance.

(d) Evidence that there is support for the project by organizations, or institutions, or employer groups which may participate in the development of the proposed health maintenance organization.

(e) A detailed report of the results of the activities performed during the feasibility survey or study which established the feasibility of developing the health maintenance organization, as well as of any other activities relating to the development of the health maintenance organization undertaken prior to application for planning assistance. With regard to the report of the feasibility survey, information on the following must be included.

(1) Status of the applicant in terms of pertinent State laws, regulations, and practices relating to operating as a health maintenance organization;

(2) Organizational structure of the proposed health maintenance organization;

(3) The types of population groups which would be sources of prepayment for an operational health maintenance organization and other potential sources of payment for services when operational;

(4) Providers of basic health services who have agreed or might reasonably

be expected to agree to provide health benefits;

(5) Sources of payment and operational support including:

(i) Preliminary estimate of the amount to be charged for basic health benefits when the proposed health maintenance organization becomes operational; and

(ii) Estimate of enrollment and income required to reach the financial breakeven point; and

(6) A preliminary estimate of facilities required for operational status.

(f) Concise plans for accomplishing planning stage activities, which must include at a minimum, a description of tasks for each activity listed below, accompanied by a time-phased milestone chart indicating proposed funding and manpower to be allocated to each such activity (where circumstances indicate that it would be appropriate and consistent with the intent of the Public Health Service Act, additional activities may be proposed):

(1) Recruitment of key project staff which shall include the employment of a full-time project director;

(2) Planning for, and when appropriate, initiation of action relating to compliance with all applicable State requirements, including State certificate of need programs, and with section 1513(e) of the Public Health Service Act;

(3) Development of formal organization;

(4) Establishment and documentation of community support;

(5) Development of a marketing plan which must include the following:

(i) Market assessment:

(A) Precise description of the service area;

(B) Information about prospects for enrollment of groups, including analysis of competing health benefits plans;

(C) Evidence of a willingness on the part of key prospects to offer the health maintenance organization when operational;

(D) An estimate of market potential for a five year period, including a five year enrollment projection.

(ii) Marketing strategy:

(A) Select the major prospects for enrollment;

(B) Develop alternatives to meet the enrollment projections;

(C) Estimate the level and type of marketing effort required to meet the enrollment projection;

(D) Develop a marketing effort and a detailed budget including staffing requirements.

(iii) Marketing materials:

(A) Develop detailed description of specifications for marketing and enrollment literature;

(B) Develop prototype membership materials including membership cards, subscriber agreements, handbooks and certificates, health questionnaires, etc.

(6) Definition of the health services and options, if any to be offered;

(7) Identification of providers of basic health services needed to provide those services to the projected enrollment, and drafting of proposed agreements to negotiate with these providers;

(8) Planning for necessary facilities and equipment and their financing;

(9) Development of premium structure;

(10) Development of budget and financial plan, including alternative plans if enrollment varies significantly from projections;

(11) Obtaining of required health systems agency or agencies and State health planning and development agency determinations; and

(12) Establishment of the individual practice association entity if appropriate to the intended organizational structure when operational as a health maintenance organization.

(g) In addition, in the case of an operational prepaid health plan which proposes to become a qualified health maintenance organization, an identification of gaps between its current operation and the requirements of §§ 417.100 through 417.109 of this subpart.

(h) In addition, in the case of a qualified health maintenance organization requesting assistance for significant expansion:

(1) Data on prepaid membership totals for annual intervals over the past five years, or if the health maintenance organization has not been operating for five years, such data on a

quarterly basis for the time during which it has been in operation;

(2) A description of the current health service delivery facilities, including an estimate of their capacity;

(3) The number and specialties of current health professionals serving its members; and

(4) The plans for the proposed significant expansion which demonstrate that the definition of significant expansion in § 417.111(c) will be met.

§ 417.123 Project elements for initial development.

An approvable application must provide:

(a) Written evidence satisfactory to the Secretary that the feasibility of the establishment and operation or expansion has been established by the applicant and that sufficient planning for the establishment or expansion has been conducted by the applicant. In addition, applicants must provide the information, assurances and evidence required by § 417.122 (a), (b), (c), (d), and (e), and must report all other activities relating to the development of the health maintenance organization undertaken prior to application for initial development assistance.

(b) Detailed plans, which must include, at a minimum, tasks designed to accomplish the activities listed below, accompanied by a time-phased milestone chart indicating proposed funding and manpower to be allocated to each (where circumstances indicate that it would be appropriate and consistent with the intent of the Public Health Service Act, additional activities may be proposed in the application):

(1) Development of a schedule to meet the requirements of §§ 417.100 through 417.109 of this subpart;

(2) Completion of activities related to resolution of legal issues;

(3) Recruitment and training of personnel essential for operation as a health maintenance organization;

(4) Development of a comprehensive financial plan;

(5) Organization of physician health services;

(6) Organization of other basic health services;

(7) Development of a schedule to construct, lease, renovate or otherwise obtain health maintenance organization facilities;

(8) Organization of ambulatory care facility;

(9) Implementation of a staffing plan that demonstrates compliance with the appropriate 15 or 30 percent limitation on contracts for basic and supplemental health services (see § 417.103(a)), and formalization of contract arrangements;

(10) Further refinement of the projected market to be served by obtaining specific evidence of employer or union willingness to offer the health maintenance organization option on specific dates;

(11) Initiation of enrollment plan; and

(12) Establishment of any working capital or reserves or both as may be required by State authorities.

(c) Evidence from physicians and from one or more hospitals indicating that they intend to become providers of basic health services for the proposed health maintenance organization:

(1) In the case of an individual practice association-type health maintenance organization, there must be such evidence from a number of physicians adequate to serve the proposed enrollment; and

(2) In the case of a non-individual practice association-type health maintenance organization, there must be such evidence from at least three physicians, indicating that they are willing to be employed by or to contract with the proposed health maintenance organization.

(d) In the case of an applicant which intends to serve Title XIX eligibles or Title XVIII beneficiaries as a part of the planned enrollment, as appropriate:

(1) Evidence that the State Title XIX agency is willing to negotiate a prepaid capitation contract in the form of a letter or other document from the State Title XIX agency; or

(2) Evidence that the applicant is planning to or has entered into a contract under Title XVIII as a health maintenance organization.

(e) In addition, in the case of an operational prepaid health plan which proposes to become a qualified health maintenance organization, an identification of gaps between its current operation and the requirements of §§ 417.100 through 417.109 of this subpart.

(f) In addition, in the case of qualified health maintenance organizations requesting assistance for expansion:

(1) Data on prepaid membership totals for annual intervals over the past five years, or if the health maintenance organization has not been operating for five years, such data on a quarterly basis for the time during which it has been in operation;

(2) A description of the current health service delivery facilities, including an estimate of their capacity;

(3) The number and specialties of current health professionals serving its members; and

(4) The plans for the proposed expansion which demonstrate that the definition of "expansion of services" or of "significant expansion" of membership or service area in § 417.111 will be met.

[43 FR 6023, Feb. 10, 1978, as amended at 45 FR 6059, Jan. 24, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.124 Funding duration and limitation.

(a) *Planning projects.* (1) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for project costs: *Provided,* That any single grant and the amount of principal of any single loan guaranteed under section 1304 of the Public Health Service Act may not exceed $200,000.

(2) In considering applications for grants for planning projects under §§ 417.120 through 417.126, the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organization becomes operational, not less than 30 percent of its members will be members of a medically underserved population. In considering applications for loan guarantees for planning projects under §§ 417.120 through 417.126, the Secretary will give special consideration to applications for projects for health maintenance organizations which will have at least 10 percent of their projected membership from medically underserved populations. Applicants may propose that the award period be for one year or less, as appropriate to the planning activities to be accomplished. Planning projects shall be completed within the period of the award. The Secretary may not make more than one additional grant or loan guarantee for a planning project for which a grant or loan guarantee has previously been made, and may permit additional time (up to 12 months) for completion of the project if he determines that the additional grant or loan guarantee (as the case may be) or additional time, or both, is needed to complete the project adequately.

(3) Funds under grants and loans guaranteed for planning projects shall be used only for the activities set forth in § 417.122(f) and for activities required to fill the gaps referred to in § 417.122(g).

(b) *Initial development projects.* (1) The aggregate amount of loan guarantees and grants for any initial development project may not exceed the amount specified by section 1304(f)(2) of the Public Health Service Act. The cumulative total of grants made to and the principal of loans guaranteed for an HMO for initial development projects may not exceed the amount specified by section 1304(f)(3) of the Public Health Service Act.

(2) A grant may only be made for initial development costs incurred in a period not to exceed three years.

(3) In considering applications for grants for initial development projects under §§ 417.120 through 417.126, the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organization becomes operational, not less than 30 percent of its members will be members of a medically underserved population. In considering applications for loan guarantees for initial development projects under §§ 417.120 through 417.126, the Secretary will give special consideration to applications for projects for health maintenance organizations which will

have at least 10 percent of their projected membership from medically underserved populations.

(4) Funds under grants and loans guaranteed for projects for initial development shall be used only for activities set forth in § 417.123(b) (except that such funds may not be used for the costs of construction or for recruitment of personnel who will not engage in practice principally for the health maintenance organization) and for activities required to fill gaps referred to in § 417.123(e).

[43 FR 6023, Feb. 10, 1978, as amended at 45 FR 6059, Jan. 24, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.125 Evaluation and award.

(a) Within the limits of funds available for such purpose, the Secretary may make awards to cover up to 90 percent of the cost of projects, or in the case of projects which will draw not less than 30 percent nor more than the appropriate percentage (as determined under § 417.107(c)) of its anticipated enrollment from medically underserved populations, up to 100 percent of the costs, to those applicants whose projects will, in his judgment, best promote the purposes of section 1304 of the Public Health Service Act and the regulations of §§ 417.120 through 417.126 taking into account:

(1) The degree to which the proposed project satisfactorily provides for the elements set forth in § 417.122 or § 417.123.

(2) The comments of the appropriate health systems agency or State health planning and development agency.

(3) Whether the feasibility of the project has been established, and in the case of initial development applications, whether all required planning activities have been accomplished.

(4) The appropriateness of the goals and objectives of the proposed project.

(5) The effectiveness the proposed organization may reasonably be expected to have in reducing inappropriate hospital utilization, containing health care costs, using medical and other health manpower, emphasizing early detection and treatment of illnesses, and achieving a better distribution and quality of care.

(6) The capability of the applicant to organize and manage the project successfully.

(7) Evidence of the applicant's intended contribution to the project.

(8) Evidence by letters or similar statements of intent from providers expressing a willineness to be employed by or contract with the proposed health maintenance organization for the provision of basic health services and evidence that providers as necessary, will contract with the health maintenance organization other than as members of its staff or through medical groups or individual practice associations.

(9) Evidence, in form of letters, from individuals, groups, or organizations indicating that they support the development and operation of the proposed health maintenance organization.

(10) The results of the Secretary's assessment of marketing capability and the prospects for eventual financial viability as an operational health maintenance organization without continued Federal support.

(11) The inclusion of medically underserved populations in groups to be enrolled.

(12) Location relative to the number of organizations providing health services to a defined population on a prepaid capitation basis, which are already operating in the area.

(13) The percentage of anticipated total enrollment to be drawn from nonmetropolitan areas to be served.

(14) In the case of an existing organization operating on a prepaid capitation basis, the applicant's potential for expeditious transition into a qualified health maintenance organization.

(15) In the case of expansion projects, the potential rate of increase of expansion, or the potential increase in the area to be served by the expanded health maintenance organization.

(b) In considering applications under §§ 417.120 through 417.126 the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organizations become operational, not less than 30 percent of their members will be members of a medically underserved population.

§ 417.126 Loan guarantee provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan guaranteed by the Secretary under §§ 417.120 through 417.126 shall be disbursed to the applicant in accordance with an agreement to be entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan guarantee, together with interest thereon, shall be repayable over a period of 22 years, beginning on the date of endorsement of the loan guarantee by the Secretary. The Secretary may however, approve a shorter repayment period where he determines that a repayment period of less than 22 years is more appropriate to an applicant's total financial plan.

(c) *Repayment.* The principal amount of each loan guarantee, together with interest thereon, shall be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan and approved by the Secretary prior to or at the time of his endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan guaranteed by the Secretary shall be repayable in substantially level combined installments of principal and interests, to be paid at intervals not less frequently than annually, sufficient to amortize the loan through the final year of the life of the loan. Principal repayment may be deferred, with payment of interest only by the applicant during a period to be specified in an agreement between the applicant and the Secretary. The Secretary may set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date the disbursement is made for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

[43 FR 6023, Feb. 10, 1978, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

LOANS AND LOAN GUARANTEES FOR INITIAL COSTS OF OPERATION

SOURCE: 43 FR 6026, Feb. 10, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.130 Applicability.

The regulations of §§ 417.130 through 417.137, in addition to the regulations of §§ 417.110 through 417.119 of this subpart, are applicable to loans and loan guarantees awarded pursuant to section 1305 of the Public Health Service Act.

§ 417.131 Definitions.

(a) "Costs of operation" means any cost incurred in the first 60 months of operation or expansion which:

(1) Under generally accepted accounting principles or under accounting practices prescribed or permitted by State regulatory authority is not a capital cost;

(2) Is required by State regulatory authority to meet reserved or tangible net equity requirements;

(3) Is for a payment made to reduce balance sheet liabilities existing at the beginning of the 60 month period, but only if (i) the payment has been approved in writing by the Secretary, and (ii) the total of these payments does not exceed 20 percent of the amount of the loan; or

(4) Is for a small capital expenditure, but only if (i) the cost has been approved in writing by the Secretary, and (ii) the total of these costs does not exceed $200,000 in any 12 month period and $400,000 during the first 60 months of operation or expansion.

(b) "First 60 months of operation or expansion" means the 60-month period beginning on the first day of the month during which the health maintenance organization first provides services to members, or in the case of significant expansion, first provides services in accordance with its expansion plan.

(c) "Any twelve month period" means the twelve month period beginning on the first day of any month.

(d) "Small capital expenditures" means expenditures for (1) equipment (as defined in 45 CFR 74.132); and (2) alterations and renovations required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment, so that it may be more effectively used for its currently designated purpose, or adapted to a changed use.

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e—300e-17))

[43 FR 6026, Feb. 10, 1978, as amended at 44 FR 10603 Feb. 22, 1979; 45 FR 6060 Jan. 24, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.132 Eligibility.

(a) *Eligible applicants.* (1) Any public qualified health maintenance organization is eligible to apply for a loan under §§ 417.130 through 417.137.

(2) Any private qualified health maintenance organization is eligible to apply for a loan or a loan guarantee under §§ 417.130 through 417.137.

(b) *Eligible projects*—(1) *Loans.* In the case of public or private qualified health maintenance organizations, loans may be made pursuant to section 1305 of the Public Health Service Act and the regulations of §§ 417.110 through 417.119 and §§ 417.130 through 417.137 to eligible applicants to assist them in meeting the amount by which their costs of operation during a period not to exceed the first 60 months of their operation exceed their revenues in such period, or in meeting the amount by which their costs of operation which the Secretary determines are attributable to significant expansion in their membership or area served, as defined in § 417.111(c), and which are incurred during a period not to exceed the first 60 months of their operation after such expansion, exceed their revenues in that period which the Secretary determines are attributable to such expansion.

(2) *Loan guarantees.* Loan guarantees may be made pursuant to section 1305 of the Public Health Service Act, and the regulations of §§ 417.110 through 417.119 and §§ 417.130 through 417.137, to guarantee to non-Federal lenders payment of the principal of and the interest on loans made to any private qualified HMO for the amounts referred to in paragraph (b)(1) of this section.

[43 FR 6026, Feb.10, 1978, as amended at 45 FR 6060, Jan. 24, 1980; 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.133 Project elements.

An approvable application must provide:

(a) Statements which describe in detail:

(1) The applicant's adequate accomplishment of feasibility survey, planning, and development activities; and

(2) The health maintenance organization's management capability.

(b) Detailed information on the health maintenance organization's marketing plan and enrollment forecasts and experience.

(c) A detailed narrative statement describing:

(1) All existing and planned provider arrangements including copies of all executed contracts; and

(2) All facilities to be used in the delivery of health services.

(d) Financial information in such detail as the Secretary may prescribe.

(e) Evidence that any certificate of need required under State law for the operation of the health maintenance organization has been obtained by the applicant.

§ 417.134 Reserve requirement.

The applicant receiving a loan or loan guarantee under section 1305 of the Public Health Service Act shall establish a restricted reserve account beginning at the point when the revenues and costs of operation of the health maintenance organization reach the break-even point, or by the end of the 60 month period following the making of the loan or the guarantee under section 1305 of the Public Health Service Act, whichever is sooner, unless a longer period is approved by the Secretary. This reserve shall be so constituted as to accumulate no later than twelve (12) years following the endorsement of the loan or loan guarantee, an aggregate amount equal to one year's principal of and interest on the loan, as determined under the terms of the loan made or guaranteed.

[43 FR 6026, Feb. 10, 1978, as amended at 45 FR 6060, Jan. 24, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.135 Evaluation and award.

Within the limits of funds available for such purposes, the Secretary may award loans or loan guarantees to those applicants whose projects will, in his judgment, best promote the purposes of section 1305 of the Public Health Service Act and the regulations of this subpart, taking into account:

(a) The ability of the health maintenance organization to achieve financial viability;

(b) The ability of the health maintenance organization to make repayments of the principal and interest when due and to have additional funds to defray the remaining operating deficits;

(c) The comments, if any, of the appropriate health systems agency or State health planning and development agency;

(d) The relative distribution of qualified applicants with respect to the following factors:

(1) The inclusion of medically underserved populations in the groups to be enrolled;

(2) Location relative to the number of organizations providing health services to a defined population on a prepaid capitation basis, which are already operating in the proposed area; and

(3) The percentage of anticipated total enrollment drawn from nonmetropolitan areas served or to be served by the applicant.

§ 417.136 Funding duration and limitation.

(a) The aggregate amount of principal of loans made to an HMO, or guaranteed for an HMO, or both, under section 1305 of the Public Health Service Act, shall not exceed the applicable maximum amounts provided in section 1305 of the Public Health Service Act. In any twelve month period, the amount disbursed to an HMO under section 1305 of the Public Health Service Act (either directly by the Secretary or by an escrow agent under the terms of an escrow agreement or by a lender under a loan guaranteed under section 1305 of the Public Health Service Act) may not exceed the maximum amounts provided in section 1305 of the Public Health Service Act.

(b) The approval of any loan or loan guarantee shall not obligate the United States in any way to make any additional loan or loan guarantee with respect to the approved application or portion thereof, except as may be otherwise set forth in the agreement between the United States and the approved applicant.

(c) In considering applications for loan guarantees under section 1305 of the Public Health Service Act and §§ 417.130 through 417.137, the Secretary will give special consideration to applications for health maintenance organizations which will serve medically underserved populations.

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e—300e-17))

[43 FR 6026, Feb. 10, 1978, as amended at 44 FR 10603, Feb. 22, 1979; 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.137 Loan provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan made or guaranteed by the Secretary under §§ 417.130 through 417.137 shall be disbursed to the applicant in accordance with an agreement to be entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan or loan guarantee, together with interest thereon, shall be repayable over a period of 22 years, beginning on the date of endorsement of the loan, or loan guarantee by the Secretary. The Secretary may, however, approve a shorter repayment period where he determines that a repayment period of less than 22 years is more appropriate to an applicant's total financial plan.

(c) *Repayment.* The principal amount of each loan or loan guarantee, together with interest thereon, shall be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan or loan guarantee and approved by the Secretary prior to or at the time of his endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan made or guaranteed by the Secretary shall be repayable in substantially level combined installments of principal and interest to be paid at intervals not less frequently than annually, sufficient to amortize the loan through the final year of the life of the loan. Principal repayment during the first 60 months of operation may be deferred, with payment of interest only by the applicant during such period. The Secretary may set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date the disbursement is made for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

[43 FR 6026, Feb. 10, 1978, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

QUALIFICATION OF HEALTH MAINTENANCE ORGANIZATIONS

SOURCE: 47 FR 31667, July 21, 1982, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.140 Applicability.

The regulations in §§ 417.140 through 417.144 apply to any entity seeking a determination by the Secretary under section 1310(d) of the Public Health Service Act that it is a qualified health maintenance organization (HMO).

§ 417.141 Definitions.

In addition to the terms defined in § 417.100 of this subpart, as used in §§ 417.140 through 417.144:

"Operational qualified "HMO" means an HMO which the Secretary has determined provides basic and supplemental health services to all of its members in accordance with §§ 417.100 through 417.109 of this subpart and is organized and operated in accordance with §§ 417.100 through 417.109 of this subpart.

"Preoperational qualified HMO" means an entity which the Secretary has determined will, when it becomes operational, be a qualified HMO.

"Transitionally qualified HMO" means an entity which operates a prepaid health care delivery system and which the Secretary has determined meets the requirements of § 417.142(b). A transitionally qualified HMO is considered a "qualified HMO" for the purpose of compliance by an employer with the requirements of section 1310 of the Public Health Service Act and §§ 417.150 through 417.159. Under these requirements, the employer must include the HMO in its health benefits plan so long as the HMO's qualification has not been revoked under section 1312(b) of the Public Health Service Act and § 417.163(d) of this subpart.

§ 417.142 Requirements for qualification.

Upon the basis of an application submitted in accordance with §§ 417.140 through 417.144 and any additional information and investigation (including site visits) that the Secretary may require:

(a) The Secretary will determine that the applicant is an operational qualified HMO upon finding that it meets the requirements of §§ 417.100 through 417.109 of this subpart and if it provides written assurances satisfactory to the Secretary, within 30 days of the date of the Secretary's determination, that it:

(1) Provides and will provide basic health services (and any contracted for supplemental health services) to its members;

(2) Provides and will provide these services in the manner prescribed by section 1301(b) of the Public Health Service Act and §§ 417.100 through 417.109 of this subpart;

(3) Is organized and operated, and will continue to be organized and operated, in the manner prescribed by section 1301(c) of the Public Health Service Act and §§ 417.100 through 417.109 of this subpart;

(4) Under arrangements which will safeguard the confidentiality of patient information and records, will provide access to the Secretary and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents,

papers, and records of the entity relating to its operations as an HMO, and to any facilities operated by the entity; and

(5) Will continue to comply with any other assurances which the entity has given to the Secretary under §§ 417.112(b) and 417.122.

(b) The Secretary may determine that an applicant is a transitionally qualified HMO upon finding that it currently is organized and is providing prepaid health services as described in this paragraph and if it provides written assurances satisfactory to the Secretary, within 30 days of the date of the Secretary's determination, that it will:

(1) With respect to all new group and individual (non-group) contracts which it enters into after the date of the Secretary's determination, provide basic health services (and any contracted for supplemental health services) to members enrolled under these contracts and will provide these services in the manner prescribed by §§ 417.100 through 417.109, and with respect to these members, will be organized and operated in accordance with § 417.107 of this subpart.

(2) With respect to its group and individual contracts which are in effect on the date of the Secretary's determination and which are renewed or renegotiated during the period approved by the Secretary under paragraph (b)(2)(iii) of this section in accordance with the plan so approved:

(i) Provide at least those services specified in the following sections of this subpart (except that these services may be limited as to time and cost): Section 417.101(a)(1) (physician services); § 417.101(a)(2) (outpatient services and inpatient hospital services) except that inpatient hospital services or outpatient services by a hospital, or both, need not be provided, or paid for by the HMO if the HMO can show that these services are, or insurance for these services is, being provided through arrangements made by entities other than the HMO; § 417.101(a)(3) (medically necessary emergency health services); and § 100.102(a)(6) (diagnostic laboratory and diagnostic and therapeutic radiologic services);

(ii) Be organized and operated in accordance with § 417.107 (except that it need not assume full financial risk for the provision of basic health services as required by § 417.107(b), and need not abide by the limitations on insurance of § 417.107(b)(1) and (3)) and provide that payment for basic health services shall be in accordance with § 417.104 (except that it need not comply with (A) the requirement for a community rating system of § 417.104(a)(3), (B) the limitations on copayments of § 417.104(a)(4), and (C) the requirement of § 417.105(b) that supplemental health services payments which are fixed on a prepayment basis be fixed under a community rating system);

(iii) Implement a time-phased plan acceptable to the Secretary which specifies definite steps for meeting, at the time of renewal of each group or individual contract, but not to exceed 3 years from the date of the Secretary's determination, all the requirements of of this §§ 417.100 through 417.109 of this subpart; and

(iv) Upon completion of the time-phased plan, (A) provide basic and supplemental health services to all of its members, (B) provide these services to all of its members in the manner prescribed by §§ 417.100 through 417.109 of this subpart, and (C) be organized and operate in the manner prescribed by §§ 417.100 through 417.109 of this subpart.

(c) The Secretary may determine that an applicant is a preoperational qualified HMO if it provides, within 30 days of the Secretary's determination, satisfactory assurances that it will become operational within 60 days following that determination and will, when it becomes operational, meet the requirements of of this §§ 417.100 through 417.109 of this subpart. Upon notification by the applicant to the Secretary that it has become operational, the Secretary will, within 30 days of this notification, make a determination whether the applicant is an operational qualified HMO. In the absence of this determination, the organization is not an operational qualified HMO even though it becomes operational.

(d) If the Secretary determines that an applicant meets the requirements for qualification and the applicant fails to sign its assurances within 30 days following the date of the determination, then the Secretary will notify the applicant in writing that its application is considered withdrawn and that is not a qualified HMO.

(e) An HMO which has more than one regional component, as described in § 417.104(b)(3)(iii), will be considered qualified for those regional components for which assurances have been signed in accordance with this section.

(Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); secs. 1301—1318 of the Public Health Service Act, as amended, 95 Stat. 572—578 (42 U.S.C. 300e—300e-17))

[47 FR 31667, July 21, 1982; 47 FR 35194, Aug. 13, 1982, as amended at 48 FR 1302, Jan. 12, 1983; 48 FR 12091, Mar. 23, 1983. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.143 Application requirements.

(a) *General requirements.* This section sets forth application requirements for entities that seek qualification as HMOs; HMOs that seek expansion of their service areas; and HMOs that seek qualification of their regional components as HMOs.

(b) *Completion of an application form.* (1) In order to receive a determination concerning whether an entity is a qualified HMO, an individual authorized to act for the entity (the applicant) must complete an application form provided by HCFA.

(2) The authorized individual must describe thoroughly how the entity meets, or will meet, the requirements for qualified HMOs described in the Public Health Service Act and in §§ 417.100 through 417.109 and 417.140 through 417.144 of this subpart.

(c) *Collection of an application fee.* In accordance with the requirements of 31 U.S.C. 9701, Fees and charges for Government services and things of value, HCFA determines the amount of the application fee that must be submitted with each type of application.

(1) The fee is reasonably related to the Federal government's cost of qualifying an entity and may vary based on the type of application.

(2) Each type of application has one set fee rather than a charge based on the specific cost of each determination. (For example, each Federally qualified HMO applicant seeking Federal qualification of one of its regional components as an HMO is charged the same amount, unless the amount of the fee has been changed under paragraph (f) of this section.)

(d) *Application fee amounts.* The application fee amounts for applications completed on or after July 13, 1987 are as follows:

(1) $18,400 for an entity seeking qualification as an HMO or qualification of a regional component of an HMO.

If, in the case of an HMO seeking qualification of a regional component, HCFA determines that there is no need for a site visit, $8,000 will be returned to the applicant.

(2) $6,900 for an HMO seeking expansion of its service area.

(3) $3,100 for a CMP seeking qualification as an HMO.

(e) *Refund of an application fee.* HCFA refunds an application fee only if the entity withdraws its application within 10 working days after receipt by HCFA. Application fees are not returned in any other circumstance, even if qualification or certification is denied.

(f) *Procedure for changing the amount of an application fee.* If HCFA determines that a change in the amount of a fee is appropriate, HCFA issues a notice of proposed rulemaking in the FEDERAL REGISTER to announce the proposed new amount.

(g) *New application after denial.* An entity may not submit another application under §§ 417.140 through 417.144 for the same type of determination for four full months after the date of the notice in which HCFA denied the application.

(h) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR Part 5, the Department's regulations providing exceptions to disclosure, should label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR Part 5.

[52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.144 Evaluation and determination of qualification.

(a) The Secretary will evaluate applications submitted under §§ 417.140 through 417.144 and will obtain any additional necessary information, employing site visits, public hearings or any other appropriate procedures. If an application is incomplete, the Secretary will notify the applicant and provide it with an opportunity to furnish the missing information within 60 days of the date of the notice. Following the evaluation of all relevant information, the Secretary will determine whether the applicant meets the appropriate requirements of §§ 417.142 and 417.143, section 1301 of the Public Health Service Act, and §§ 417.100 through 417.109 of this subpart.

(b) Upon finding that an applicant (1) does not appear to meet the requirements for qualification and (2) appears to be able to meet the requirements within 60 days, the Secretary will issue to the applicant a notice of intent to deny qualification and a summary of the basis for this preliminary finding. Within 60 days of the date of this notice, the applicant may respond in writing to the issues or other matters which were the basis for the Secretary's preliminary finding, and may revise its application to remedy any defects identified by the Secretary.

(c) The Secretary will notify each applicant for qualification under §§ 417.140 through 417.144 of the determination and the basis for the determination.

(d) Upon the denial of an application for qualification under §§ 417.140 through 417.144, the Secretary will notify the applicant in writing and provide the applicant an opportunity to request a reconsideration of the determination. A request for reconsideration must be submitted in writing, within 60 days following the date of the notification of denial, be addressed to the officer or employee of the Department of Health and Human Services who has denied the application, and set forth the grounds upon which the reconsideration is requested, specifying the material issues of fact and of law upon which the applicant relies. Reconsideration will be based upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to the Secretary. The Secretary will provide written notice of the reconsidered determination to the applicant. The notice will set forth the basis for the determination.

(e) The Secretary will publish on a monthly basis in the FEDERAL REGISTER the names, addresses, and descriptions of the service areas of the newly qualified HMOs. A cumulative list of qualified HMOs may be obtained by writing the Document Control Unit, Office of Health Maintenance Organizations, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, or by visiting that Office between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. Interested persons should contact that Office between 8:00 a.m. and 4:30 p.m., Monday through Friday, to make an appointment to obtain additional information regarding qualified HMOs.

[47 FR 31667, July 21, 1982; 47 FR 35194, Aug. 13, 1982]

EMPLOYEES' HEALTH BENEFITS PLANS

SOURCE: 45 FR 72517, Oct. 31, 1980, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.150 Definitions.

In addition to the terms defined in §§ 417.100 and 417.141, as used in §§ 417.150 through 417.159:

"Bargaining representative" means a representative designated or selected for the purposes of collective bargaining under the National Labor Relations Act, as amended, (29 U.S.C. 151 *et seq.*) or under the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or under a public entity collective bargaining agreement, or under the laws of any State or political subdivision thereof, or other employee representative designated or selected under any law.

"Carrier" means a voluntary association, corporation, partnership, or other organization which is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

"Collective bargaining agreement" means an agreement entered into between an employing entity and the bargaining representative of its employees, and includes agreements entered into on behalf of groups of employing entities with the bargaining representative of their employees in accordance with the provisions of the National Labor Relations Act, as amended (29 U.S.C. 151 *et seq.*), or the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or the laws of any State or political subdivision thereof.

"Designee" means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of membership in a qualified health maintenance organization to their eligible employees.

"Eligible employee" means an employee who is eligible to participate in a health benefits plan.

"Employee" means any individual employed by an employer or public entity on a full- or part-time basis.

"Employer" shall have the meaning given that term in section 3(d) of the Fair Labor Standards Act of 1938, as amended, (29 U.S.C 203(d), 203(x)), except that the term "employer" includes non-appropriated fund instrumentalities of the Government of the United States, but does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Rate Commission) of any of the foregoing; or (2) a church, convention or association of churches, or any organization operated, supervised, or controlled by a church, convention, or association of churches which organization (i) is an organization described in section 501(c)(3) of the Internal Revenue Code of 1954, and (ii) does not discriminate (A) in the employment, compensation, promotion, or termination of employment of any personnel, or (B) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through an HMO.

"Employing entity" means an employer or public entity.

"Employing entity-employee contract" means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

"Group enrollment period" means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

"Health benefits" means health benefits and services.

"Health benefits contract" means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment for, health benefits to eligible employees or to eligible employees and their eligible dependents.

"Health benefits plan" means any arrangement for the provision of, or payment for, any of the basic and supplemental health benefits described in §§ 417.101 and 417.102 of this subpart offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

"Public entity" means a State as defined by section 2(f) of the Public Health Service Act (42 U.S.C. 201(f)), a political subdivision of a State, or any agency or instrumentality of the foregoing. "Political subdivision" includes counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

"To offer a health benefits plan" means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents, and to make a financial contribution to the plan whether the financial contribution by the employing entity on behalf of these employees is made directly or indirectly, (e.g. through payments on any basis into a health and welfare trust fund).

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982; Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.151 Applicability.

The regulations in §§ 417.150 through 417.159 apply in each calendar year to:

(a) Each employer which was required during any calendar quarter of the previous calendar year to pay its employees the minimum wage specified by section 6 of the Fair Labor Standards Act of 1938 (or would have been required to pay its employees the minimum wage but for section 13(a) of that Act) and which during any calendar quarter of the previous calendar year employed an average of not less than 25 employees; and

(b) Each public entity, as a condition of the payment to the State of funds under sections 314(d), 317, 318, 1002, 1525, or 1610 of the Public Health Service Act, which during any calendar quarter of the previous calendar year employed an average of not less than 25 employees, if the employer or public entity:

(1) Offers, or if there is offered on behalf of the employer or public entity, in the calendar year beginning after any calendar quarter of the previous calendar year in which the employer or public entity employed an average of not less than 25 employees, a health benefits plan to its eligible employees; and

(2) Has received a written request for inclusion in the employer's or public entity's health benefits plan (which request meets the requirements of § 417.152) from one or more qualified HMOs which provide basic health services in an HMO service area in which at least 25 employees of the employer or the public entity, respectively, reside.

§ 417.152 Requirements for a request for inclusion of the HMO option in a health benefits plan; employing entity response.

(a) *Time limitations.* (1) Unless otherwise agreed to by the HMO and the employing entity or designee, an HMO's request for inclusion in an employing entity's health benefits plan must be received by the employing entity or designee no more than 365 days and not less than 180 days before the expiration or renewal date of a health benefits contract or employing entity-employee contract, and no more than 365 days and not less than 180 days before the expiration date of a collective bargaining agreement, or in the case of a public entity, such longer period as may be prescribed by State law.

(2) For the purposes of this paragraph:

(i) A collective bargaining agreement that is automatically renewable or without fixed term shall be treated as having an expiration or renewal date on the earliest anniversary date of the collective bargaining agreement.

(ii) A collective bargaining agreement that is for a fixed term in excess of one year and provides that its terms regarding health benefits may be renegotiated during the term of the agreement shall be treated as having an expiration or renewal date at the time provided by the agreement for discussion of these changes.

(b) *To whom the written request is to be directed.* The request for inclusion must be in writing and (1) in the case of an employer, be directed specifically to the employer's managing official at the employer site being solicited or to the employer's designee; and (2) in the case of a public entity, be directed to the Chief Executive Officer of the public entity, or to the public entity's designee.

(c) *Information which the request must include.* The request must (1) Provide evidence that the Secretary has determined that the HMO is a qualified HMO in accordance with sec-

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tion 1310(d) of the Public Health Service Act and §§ 417.140 through 417.144 of this subpart;

(2) Describe the HMO's service area or proposed service area and give the dates basic and supplemental health services will be provided in the area or areas;

(3) Indicate whether the services of health professionals which are provided as basic health services are provided through health professionals who are (i) members of the staff of the organization, or (ii) members of a medical group(s), or (iii) members of an individual practice association(s), or (iv) health professionals who have contracted with the HMO for the provision of these services or (v) any combination of the above;

(4) If the HMO provides health services through an individual practice association(s), provide a listing of member physicians by name, specialty, and whether they are accepting new patients from the HMO membership. This listing must be current within 90 days of the date of the request for inclusion;

(5) If the HMO provides health services other than through an individual practice association, provide for each ambulatory care facility the facility's address, days and hours of operation, a statement whether it is accepting new patients from the HMO membership, and the names and specialities of the facility's providers of basic and supplemental health services. This information must be current within 90 days of the date of the request for inclusion;

(6) List the hospitals where HMO members will be provided basic and supplemental health services;

(7) Identify (i) the nature of the HMO entity, i.e., for profit or nonprofit, public or private, sole proprietorship, partnership, or stock or nonstock corporation, (ii) the members of the HMO's policymaking body, and (iii) the principal managing officer of the HMO;

(8) Provide a statement of the HMO's capacity to enroll new members and the likelihood of any future limitations on enrollment;

(9) Provide the HMO's most recently audited annual financial statements;

(10) Provide proposed implementing agreements between the HMO and the employer, public entity, or designee for the HMO offering;

(11) Provide sample copies of solicitation brochures and membership literature which will be used in the offer of the HMO alternative to employees;

(12) State either (i) the HMO's current rates, including copayments, if any, for basic (and uniformly included supplemental) health services and the dates these rates became effective, or (ii) the HMO's estimated rates for these services.

(d) *Employing entity response.* An employing entity or designee shall respond in writing to an HMO's request for inclusion no later than 60 days after the receipt of the request and shall state whether the employing entity has 25 or more employees who reside within the service area of the HMO. If so, the employing entity or designee shall also state the expiration or renewal dates of its health benefits contracts, employer-employee contracts, and public entity-employee contracts covering these employees, the amount of the employing entity's current contribution (and, where applicable, the employee's contribution) for health benefits, including the dates those contribution levels became effective, and the expiration dates of any collective bargaining agreements covering these employees. In addition, in this response, a public entity or its designee shall furnish the HMO with a description of health benefits, including limitations and exclusions, required under State law or regulation for health benefits plans for employees of the public entity.

(e) *Effect of inadequate request.* If the request for inclusion does not meet the requirements of paragraphs (a) through (c) of this section, the employing entity is not required to include the HMO alternative in its employees' health benefits plan under § 417.154 until the HMO makes its request in accordance with those paragraphs. In such a case, the employing entity or its designee shall, within 60 days after receipt of the request, notify the HMO in writing of the basis for its conclusion that the request does not meet the requirements of paragraphs (a) through (c) of this section.

(f) *New request for inclusion.* If an employing entity includes the HMO alternative in a health benefits plan in accordance with a request meeting the requirements of paragraphs (a) through (c) of this section, the employing entity shall offer the HMO alternative to the employees described in § 417.155(e)(2) during the entire health benefits year. However, if no employees enroll during the health benefits year, the HMO seeking inclusion in the health benefits plan for subsequent enrollment periods shall submit a new request in accordance with paragraphs (a) through (c) of this section.

[45 FR 72517, Oct. 31, 1980, as amended at 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.153 Offer of HMO option to employees.

(a) *Inclusion of HMO option.* An employing entity subject to § 417.151 shall, at the time a health benefits plan is offered to its eligible employees, include in the plan the option of membership in qualified HMOs in accordance with this section.

(b) *Employees to whom the HMO option must be offered.* Each employing entity subject to §§ 417.150 through 417.159 shall offer the option of membership in a qualified HMO to each eligible employee, or to each eligible employee and his or her eligible dependents, who reside within the service area of the qualified HMO being offered.

(c) *Manner of offering the HMO option.* (1) For the employees of an employing entity subject to §§ 417.150 through 417.159 who are represented by a bargaining representative, the offer of membership in a qualified HMO (i) must first be made to the bargaining representative, and (ii) if the offer is accepted by the representative, must then be made to each represented employee.

(2) For those employees not represented by a bargaining representative, the offer must be made directly to those employees in accordance with §§ 417.150 through 417.159.

§ 417.154 HMOs which must be included in a health benefits plan.

(a) *HMOs providing basic health services through varying arrangements with health professionals.* If more than one qualifed HMO engaged in the provision of basic health services in an area in which eligible employees of an employing entity subject to §§ 417.150 through 417.159 reside has requested inclusion in the employer's or public entity's health benefits plan as provided by § 417.151, and if:

(1) One or more of these organizations provides more than one-half of its basic health services through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups), and

(2) One or more of these organizations provides its basic health services which are provided by physicians through (i) an individual practice association (or associations), or (ii) a combination of such an association (or associations), medical group (or groups), staff, and individual physicians and other health professionals under contract with the organization, then, of the qualified HMOs included under this section in a health benefits plan of an employing entity subject to §§ 417.150 through 417.159, at least one shall be an organization which provides basic health services as described in paragraph (a)(1) of this section and at least one shall be an organization which provides basic health services as described in paragraph (a)(2) of this section. For purposes of this paragraph, individual physicians and other health professionals who have contracted with the HMO do not include health professionals who are members of the HMO's staff, of medical groups, or of entities which would be medical groups but for the requirements of paragraph (3)(i) of the definition of medical group in § 417.100.[1]

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[1] These requirements are that the members of the medical group "as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their profes-

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(b) *Additional HMOs which must be included.* An employing entity subject to §§ 417.150 through 417.159 shall offer the option of membership in additional qualified HMOs to its eligible employees, described in paragraphs (b)(1) and (2) of this section, if the additional qualified HMOs demonstrate that their service areas include the place of residence of at least 25 employees of the employing entity:

(1) Who do not reside in the service area of qualified HMOs already included in the employing entity's health benefits plan; or

(2) To whom membership in qualified HMOs already included in the health benefits plan is not available because these HMOs have closed their enrollment of additional eligible employees of the employing entity.

(c) *Alternate HMOs which may be included.* An employing entity subject to §§ 417.150 through 417.159 is not required to include in the health benefits plan offered to eligible employees the option of membership in the specific qualified HMO which initiated the request for inclusion in the health benefits plan if (1) the employing entity or designee includes in the health benefits plan the option of membership in one or more other qualified HMOs that may not have made a request within the time limit of § 417.152(a) but are willing to be included, (2) these latter HMOs are of the same type (i.e., as described in paragraph (a)(1) or (2) of this section) as the HMO which submitted the timely request, and (3) all of the employees of the employing entity residing in the service area of the HMO submitting the timely request reside in areas served by these latter HMOs.

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982; 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.155 How the HMO option is to be included in the health benefits plan.

(a) *HMO access to employees.* The employing entity shall provide each qualified HMO which is included in its health benefits plan with fair and reasonable access, not less than 30 days prior to and during the group enrollment period, to employees referred to in § 417.153(b) for purposes of presenting and explaining its program in accordance with § 417.107(c) of this subpart. This access shall include, at a minimum, the opportunity for the distribution of educational literature, brochures, announcements of meetings, and other relevant printed materials meeting the requirement of § 417.107(c) to each employee referred to in § 417.153(b). In no event shall the employing entity provide qualified HMOs access to eligible employees which is more restrictive or less favorable than the access it provides other offerors of alternatives included in the health benefits plan, whether or not these offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* The HMO shall give the employing entity or designee the opportunity to review, revise, and approve HMO educational and offering materials before distribution. Revisions shall be limited to correcting factual errors and misleading or ambiguous statements, unless otherwise agreed to by the HMO and the employer or public entity or designee, or as may be required by law. The employing entity or designee shall complete promptly any of these revisions in the offering material so as not to delay or otherwise interfere with the group enrollment period.

(c) *Group enrollment period; prohibition of waiting periods, exclusions, and limitations.* An employing entity or designee including the option of membership in a qualified HMO under §§ 417.150 through 417.159 as subpart of the health benefits plan offered to its eligible employees shall provide for a group enrollment period, prior to the effective date of the HMO coverage established under paragraph (g) of this section, without application of waiting periods or exclusions or limitations based on health status as a condition of enrollment in the HMO or transfer to non-HMO coverage from an HMO. Nothing in §§ 417.150 through 417.159 precludes the uniform application of coordination of benefits agreements between the HMOs and the other car-

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sional activity) for the delivery of health services to members of an HMO."

riers which are included in the health benefits plan.

(d) *Continued availability of other health benefits.* (1) At the request of a qualified HMO, the employing entity or its designee shall provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and which are not included in the services provided by the HMO to its members as part of the HMO prepaid benefit package.

(2) For purposes of this paragraph, the term "free-standing" refers to a benefit which (i) is not integrated or incorporated into a basic health benefits package or major medical plan, and (ii) is either (A) offered by a carrier other than the one offering the basic health benefits package or major medical plan, or (B) subject to a separate premium from the premium for the basic health benefits package or major medical plan.

Illustrative Examples: Set forth below are examples of the employing entity's obligation with respect to the continued eligibility of employees selecting the HMO option for these free-standing health benefits:

1. The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide for the continued eligibility of those employees selecting the HMO option for dental coverage.

NOTE: If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.

2. If the non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eye glasses), and the HMO does not, the employing entity must provide for the continued eligibility for those employees selecting the HMO option for optical coverage.

3. The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its prepaid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide for the continued eligibility for dental coverage for those employees selecting the HMO option, although it is free to do so.

(e) *Affirmative written selections.* (1) During the group enrollment period in which the alternative of membership in any particular qualified HMO is offered to an eligible group of employees for the first time, the employing entity or designee shall present the health benefits plan alternatives to each eligible employee residing in the service area of the HMO with the requirement that an affirmative written selection be made among the different alternatives included in the health benefits plans. In subsequent group enrollment periods, it shall make available a selection among the alternatives; however, a written selection is required only when the eligible employee elects to change from one alternative to another.

(2) In addition to the group enrollment period, the employing entity or designee shall make available the opportunity to select among different existing alternatives within a health benefits plan to eligible employees who: (i) Are new employees, (ii) have been transferred or have changed their place of residence, resulting in eligibility for membership in a qualified HMO for which they were not previously eligible by place of residence, or resulting in residence outside the service area of a qualified HMO in which they were previously enrolled, or (iii) are covered by any alternative which ceases operation. At the time these employees are eligible to participate in the health benefits plan, the employing entity or designee shall make available, without waiting periods or exclusions or limitations based on health status as a condition, the opportunity to enroll in an alternative HMO or transfer to a non-HMO coverage from an HMO, and shall require these employees to make an affirmative written selection among the different alternatives included in the health benefits plan.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for is to be made as follows:

(1) For those employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For those employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services to be offered to eligible employees is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO alternatives in its health benefits plan.

(3) In all cases, the HMO has the right to include with its basic health services provided to its members for a basic health services payment, on a non-negotiable basis, those supplemental health services (i) that are required to be offered under State law, or (ii) that are included uniformly by the HMO in its prepaid benefit package, or (iii) coverage for which is available to employees selecting the non-HMO option but not available to employees selecting the HMO option.

(g) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, the effective date of coverage by the HMO for employees selecting the HMO option shall begin on the day the non-HMO coverage expires or is renewed without lapse.

§ 417.156 When the HMO is to be offered to employees.

The employing entity or designee shall offer eligible employees the option of membership in a qualified HMO at the earliest date permitted under the terms of existing collective bargaining agreements, employer-employee or public entity-employee contracts, or contracts for health benefits. Should the HMO's request for inclusion in a health benefits plan be received at a time when these existing contracts or agreements do not provide for including a qualified HMO in the health benefits plan, the inclusion of the HMO in the health benefits plan shall occur at the time that new agreements or contracts are offered or negotiated and shall be consistent with the following paragraphs:

(a) Unless mutually agreed otherwise, if a collective bargaining agreement is in force at the time the request for inclusion in the health benefits plan is made by the HMO to the employing entity or designee, the request shall be raised in the collective bargaining process (1) when a new agreement is negotiated, (2) if the agreement is for a fixed term in excess of one year and provides that its terms regarding health benefits may be renegotiated during the term of the agreement, at the times provided by the agreement for discussion of these changes, or (3) in accordance with a specific process to review HMO offers.

(b) Unless mutually agreed otherwise, for those employees not covered by a collective bargaining agreement, the employing entity or designee shall include the HMO option in any health benefits plan offered to eligible employees when the existing employer-employee contract or public entity-employee contract is renewed or when a new health benefits contract or other arrangement is negotiated. If an employer-employee or public entity-employee contract or a health benefits contract has no fixed term or has a term in exess of one year, the contract shall be treated as renewable on its earliest anniversary date. If the employing entity or designee is self-insured, the budget year shall be treated as the term of the existing contract.

(c) Unless mutually agreed otherwise, for employing entities with multiple contracts or other arrangements included as part of the health benefits plan which may have different expiration or renewal dates, the employing entity shall include the HMO option, in accordance with paragraphs (a) and (b) of this section, for each contract or arrangement at the time the contract or arrangement is renewed or reissued or the benefits provided under the contract or arrangement are offered to employees.

§ 417.157 Contributions for HMO option.

(a) *General principles.* (1) The employing entity or designee shall include the HMO option in the health benefits plan on terms no less favorable, with respect to the employing entity's monetary contribution or designee's cost for health benefits calculated in dollars and cents, than those on which the other alternatives in the health benefits plan are included. However, the employing entity or designee is not required to pay more for health benefits as a result of offering the option of membership in a qualified HMO than it would otherwise be required to pay for health benefits by a collective bargaining agreement or other employer-employee contract or public entity-employer contract in effect at the time the HMO is included in the health benefits plan.

(2) An employing entity or designee which calculates the health benefits contribution on a per employee earnings level basis must apply that same calculation to the HMO contribution. The amount of the employing entity's or designee's contribution per employee for the HMO option must be equal, in terms of dollars and cents, to the largest amount of the contribution that would be paid for that individual employee to any other alternative which is included in the health benefits plan, but shall not be required to exceed the amount of the HMO premium.

(3) The employing entity or designee shall increase the amount of its contribution for the HMO option at the time the contribution to other alternatives in the health benefits plan increases (up to the amount of the HMO premium), unless (i) the employing entity's or designee's contribution is fixed by a contract or other arrangement between the employing entity or designee and the HMO, or (ii) otherwise agreed to by the employing entity or designee and the HMO.

(b) *Administrative expenses.* The employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan in determining the amount of its contribution to the HMO. However, if the employing entity or designee has special requirements for other than standard solicitation brochures and membership literature, it shall determine and distribute any administrative costs attributable to these requirements, in the case of the offering of the HMO option, in a manner consistent with its method of determining and distributing these costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or designee's cost for the HMO option, the employing entity or designee may exclude those portions of the contribution allocable to benefits (e.g., life insurance or insurance for supplemental health benefits) for which eligible employees or eligible employees and their eligible dependents will be covered notwithstanding selection of membership in an HMO, and which are not offered on a prepaid basis by the HMO to the employing entity's employees.

(d) *Contributions determined by collective bargaining agreements or by other contracts or by law.* Where the specific amount of the employing entity's contribution for health benefits is fixed by a collective bargaining agreement, by an employer-employee or public entity-employee contract, or by law, the amount so determined shall constitute the employing entity's obligation for contribution toward the HMO premiums on behalf of eligible employees or eligible employees and their eligible dependents.

(e) *Allocation of portion of a contribution determined by a collective bargaining agreement.* Where the employing entity's contribution for health benefits is determined by a collective bargaining agreement, but the amount so fixed includes contribution for benefits in addition to health benefits, the employing entity shall determine, or shall instruct its designee to determine, the portion of its contribution applicable to health benefits in accordance with paragraph (g) of this section.

(f) *Contributions not determined by collective bargaining agreements or by other contracts or by law.* For employees not covered by a collective bargaining agreement, employer-employee or public entity-employee contract, or by a law specifying the contribution for health benefits, the employing entity's contribution to the HMO on behalf of eligible employees or eligible employees and their eligible dependents shall be determined in accordance with paragraphs (a), (b), (c), and (g) of this section on the basis of the total cost of providing the health benefits offered to the employees for the most recent period for which experience is available.

(g) *Calculation of cost.* An employing entity's contribution or designee's cost for alternatives other than the qualified HMO, included in the health benefits plan shall be determined in the following manner, unless otherwise agreed to by the HMO and the employing public entity or designee:

(1) *Prospective calculation.* If the employing entity's contribution or designee's cost for non-HMO alternative health benefits is determined solely on the basis of a fixed prospective amount (not subject to retrospective adjustment) then the amount of the prospective payment made by or on behalf of the employing entity to the non-HMO alternative for the provision of health benefits to eligible employees or to eligible employees and their eligible dependents shall constitute the employing entity's contribution toward the HMO premium.

(2) *Retrospective calculation.* If the employing entity's contribution or designee's cost for non-HMO alternative health benefits is determined by a contract with a carrier on any form of retrospective experience rating basis, including any determination of current premiums which reflects, takes into account, or is otherwise based on any form of supplementation or any rebate, refund or other redistribution of premiums collected in any previous year for which experience is available, any billing contract arrangement, any plan of self-insurance, any direct service plan provided by the employing entity or designee, or any other form of health benefits plan wherein the actual cost to the employing entity or designee is determined retrospectively, an estimated cost shall be used to determine the obligation for contribution toward the HMO premium. The employing entity or designee shall determine this estimated cost based on consideration of the following factors: (i) The employing entity's or designee's cost experience for the non-HMO alternatives with respect to the most recent benefit period for which the experience is available at the time when the employing entity's prospective contribution or designee's obligation to the HMO is to be determined; (ii) a reasonable allowance for inflation based on historical cost trends and the anticipated future costs increases; (iii) where applicable and consistently applied, cost differences experienced in the provision of health benefits for separate regional or local areas of employment; (iv) anticipated changes in the composition and experience of the covered population actually being served by the non-HMO alternatives attributable to the shift of enrollment to the HMO; (v) any changes in health benefits to be provided by the non-HMO alternatives during the period for which the estimated contribution is to be determined; (vi) any other anticipated material change in the experience rating basis under any health benefits contract for the benefits period.

(h) *Retention of data.* An employing entity or designee shall retain the data used to compute its level of contribution to the alternatives included in the health benefits plan for three years. The Secretary may review this data either on her own initiative or in response to a request to the Secretary from an HMO or an employee of the employing entity which sets forth reasonable grounds supporting the request to determine whether the level of contributions determined by the employing public entity or designee complies with §§ 417.150 through 417.159.

§ 417.158 Payroll deductions.

Each employing entity which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required, and which is required by § 417.151(a) to offer its employees the option of membership in a qualified HMO, shall, with the consent of an employee who exercises this option, arrange for the employee's contribution, if any, for HMO membership to be paid through payroll deductions.

§ 417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act, as amended, and the Railway Labor Act, as amended.

The obligation of an employing entity subject to §§ 417.150 through 417.159 to include the option of membership in a qualified HMO in any health benefits plan offered to its eligible employees shall be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway Labor Act, and other laws of similar effect.

CONTINUED REGULATION OF HEALTH MAINTENANCE ORGANIZATIONS AND OTHER ENTITIES

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.160 Purpose and applicability.

Sections 417.160 through 417.166 applies to any entity which was determined by the Secretary to be a qualified health maintenance organization (HMO) under §§ 417.140 through 417.144 of this subpart, or which provided written assurances to the Secretary as a condition for receiving financial assistance under §§ 417.120 through 417.126 or §§ 417.130 through 417.137 of this subpart, and sets forth procedures for enforcing the assurances given to the Secretary by these entities.

§ 417.161 Compliance with assurances.

Any entity subject to §§ 417.160 through 417.166 shall comply with the assurances which it provided to the Secretary, unless compliance is waived under § 417.166.

§ 417.162 Reporting requirements.

Entities subject to §§ 417.160 through 417.166 shall submit:

(a) The reports which may be required by the Secretary under § 417.107(j), and,

(b) Any additional reports the Secretary may reasonably require.

[43 FR 32255, July 25, 1978, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.163 Enforcement procedures.

(a) *Complaints.* Any person, group, association, corporation, or other entity may file a written complaint with the Secretary with respect to the compliance of any entity with assurances it gave to the Secretary under this subpart. A complaint shall state the grounds and underlying facts of the complaint, the names of all persons involved, and that all appropriate grievance and appeals procedures established by the entity and available to the complainant have been exhausted.

(b) *Investigations.* The Secretary may initiate investigations when, based on a report, a complaint, or any other information, he has reason to believe that an entity subject to §§ 417.160 through 417.166 is not in compliance with any assurances it gave to the Secretary under this subpart. The Secretary will notify the entity in writing when an investigation has been initiated. He will include in this notice a full statement of the pertinent facts and of the matters being investigated, and a statement that the entity may submit to him within 30 days from the date of the notice a written report concerning these matters. The Secretary will obtain any information he considers necessary to determine the issues and may employ site visits, public hearings, or any other procedures he considers appropriate to obtain this information.

(c) *Determinations and notifications by the Secretary*—(1) *Determinations.* On the basis of his investigation, the Secretary will determine whether the entity has failed to comply with any assurances it gave to the Secretary under this subpart. The Secretary will publish in the FEDERAL REGISTER a notice regarding each determination of noncompliance. In the case of a qualified HMO, a determination of noncompliance shall not affect its status as a qualified HMO, unless the Secretary makes the further determination described in paragraph (d)(1) of this section.

(2) *Notification of determination; corrective action.* The Secretary will notify the entity in writing of his determination. This notice shall specify the manner in which the entity has not complied with its assurances and shall direct the entity to initiate corrective action which the Secretary deems necessary to bring the entity into compliance. The entity shall initiate this corrective action within 30 days of the date on which the notice is issued by the Secretary or within any longer period which the Secretary determines to be reasonable and specifies in the notice. The entity shall carry out the corrective action within the period specified for that purpose by the Secretary. In the notice, the Secretary may provide the entity an opportunity to submit for his approval proposed methods for achieving compliance.

(d) *Remedies*—(1) *Qualified HMO's:* If the Secretary determines that a qualified HMO (A) has failed to initiate corrective action in accordance with paragraph (c)(2) of this section, or (B) has not carried out or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, the Secretary will, for purposes of section 1310 of the Public Health Service Act, revoke the HMO's qualification and will notify the HMO of this action. In this notification, the Secretary shall provide the HMO with an opportunity for reconsideration of the revocation, including at the HMO's election a fair hearing. The revocation of qualification shall be effective on the tenth calendar day after the date of the notice unless the Secretary receives a request for reconsideration by that date. If, upon reconsideration, the Secretary again determines to revoke the HMO's qualification, this revocation shall be effective on the tenth calendar day after the date of the notice of the reconsidered decision. The Secretary shall publish in the FEDERAL REGISTER each determination under this paragraph. A revocation under this paragraph shall have the effect described in § 417.164. Within 15 days after the date a notice of revocation is issued by the Secretary, the HMO shall, in a notice written in readily understandable language, describe the reasons for the determination that it is not a qualified HMO and shall send the notice to:

(i) The members of the HMO;

(ii) Each employer or public entity which has offered membership in the HMO in compliance with section 1310 of the Public Health Service Act; and

(iii) Each lawfully recognized collective bargaining representative or other employee representative which represents the employees of the employer or public entity.

(2) *Other entities.* If, in the case of an entity which received a grant, loan, or loan guarantee under this subpart, the Secretary determines that it (A) has failed to initiate corrective action in accordance with paragraph (c)(2) of this section, or (B) has not carried out or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, he may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with any assurances it furnished the Secretary respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made in connection with its application under Title XIII for the grant, loan, or loan guarantee.

(3) *Reimbursement of members for services improperly denied or for charges improperly imposed.* If, in the case of an HMO with respect to which a determination of non-compliance has been made under paragraph (c)(1) of this section the Secretary also finds that the HMO has failed to provide or arrange for health services for its members in accordance with assurances given by the HMO to him under this subpart, or that the HMO has provided health services but has charged the member in a manner inconsistent with these assurances, he may, in addition to the remedies listed in paragraph (d) (1) and (2) of this section, require the HMO to reimburse its members for the expenses of securing

basic or supplemental health services which because of this noncompliance the members obtained other than through the HMO or for which it charged the member. The provisions of this subparagraph shall apply without regard to when the HMO failed to comply with the appropriate assurances.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17))

[43 FR 32255, July 25, 1978, as amended at 47 FR 19341, May 5, 1982; 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.164 Effect of revocation of qualification for purposes of section 1310 of the Public Health Service Act.

When an HMO's qualification is revoked under § 417.163(d)(1):

(a) The HMO may not seek inclusion in employees' health benefits plans under §§ 417.150 through 417.159 of this subpart.

(b) With respect to employers including the HMO in the health benefits plan offered their employees, the HMO is not a qualified HMO for purposes of §§ 417.150 through 417.159 subpart. Following the effective date of revocation, the inclusion of the health maintenance organization in an employees' health benefits plan will be disregarded for purposes of determining whether, and to what extent, the employer is subject to §§ 417.150 through 417.159 of this subpart, and will not constitute compliance with the requirement of §§ 417.150 through 417.159 of this subpart.

(c) The HMO is not a qualified HMO for purposes of the financial assistance programs under §§ 417.120 through 417.126 and 417.130 through 417.137 of this subpart until it is, in accordance with § 417.165, again qualified under §§ 417.140 through 417.144 of this subpart.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17))

[43 FR 32255, July 25, 1978, as amended at 50 FR 6176, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.165 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by the Secretary for purposes of section 1310 of the Public Health Service Act may, after completing the corrective action required under § 417.163(c)(2), reapply for a determination of qualification in accordance with the procedures specified in §§ 417.140 through 417.144 of this subpart.

§ 417.166 Waiver of assurances.

The Secretary may release an entity from compliance with any assurances given under this subpart for good cause shown, consistant with the purpose of Title XIII of the Public Health Service Act, except that upon the waiver of any assurance regarding the HMO's compliance with section 1301 of the Public Health Service Act, the Secretary will revoke the qualification of the HMO unless the waiver is based on paragraph (c) of this section. Grounds upon which the Secretary will find good cause include, but are not limited to, the following:

(a) The entity has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances;

(b) State laws governing the entity have been changed after it signed the assurances so as to prohibit the entity from being organized and operated in a manner consistent with the signed assurances, except to the extent that the changes would be superseded under the authority of section 1311 of the Public Health Service Act; or

(c) Qualification requirements have been changed by a law of the United States.

LOANS AND LOAN GUARANTEEES FOR ACQUISITION AND CONSTRUCTION OF AMBULATORY HEALTH CARE FACILITIES

SOURCE: 45 FR 24353, Apr. 9, 1980, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.170 To what loans and loan guarantees do these regulations apply?

The regulations of §§ 417.170 through 417.180, in addition to the regulations of §§ 417.110 through 417.119 of this subpart, apply to loans and loan guarantees awarded to HMOs under section 1305A of the Public Health Service Act. These loans and loan guarantees are for projects for the acquisition of, the construction of, or the acquisition of equipment for, ambulatory health care facilities.

§ 417.171 Definitions.

In addition to the terms defined in § 417.100 of this subpart:

"Ambulatory health care facility" or "facility" means a health care facility for the provision of diagnostic, treatment, and prevention services to ambulatory patients. If a facility occupies a portion of a building, the other parts of which are not owned by the HMO, the term does not include those other parts of the building. If an HMO is located in several buildings, each building in which the HMO provides diagnostic, treatment, and prevention services to ambulatory patients is a facility.

"Construction" means (a) the construction of new facilities; (b) the alteration, expansion, remodeling, replacement, and renovation of existing facilities; (c) off-site improvements in connection with an activity described in clause (a) or (b); and (d) the acquisition of land in connection with an activity described in clause (a), (b), or (c).

"Equipment" means those items which are necessary for the functioning of a facility acquired or constructed with a loan or loan guarantee awarded under §§ 417.170 through 417.180, but does not include items of current operating expense such as food, fuel, pharmaceuticals, dressings, paper, printed forms and housekeeping supplies.

"Net assignable square footage" means the sum of all useable floor space measured on a floor plan to the inside faces of all enclosing walls or to lines denoting functional separations. Net assignable square footage includes all rooms to which a specific use can be assigned and excludes corridors, lobbies, toilets, mechanical shafts, ducts, electrical shafts or closets, elevators or elevators shafts, columns, exterior walls or partitions, service rooms, custodial supplies and general storage areas.

"Title" when used with reference to a facility which is proposed to be acquired or constructed with assistance under §§ 417.170 through 417.180, means a fee simple or any other estate or interest (including a leasehold) which the Secretary finds sufficient to assure, for a period of not less than the repayment period of the loan to be made or guaranteed by the Secretary, undisturbed use and possession for the purposes of acquisition, or construction, and operation of the project.

§ 417.172 What organizations are eligible for loans and loan guarantees?

(a) Any public health maintenance organization which is qualified under §§ 417.140 through 417.144 of this subpart is eligible to apply for a loan under §§ 417.170 through 417.180.

(b) Any private health maintenance organization which is qualified under §§ 417.140 through 417.144 of this subpart is eligible to apply for a loan or a loan guarantee under §§ 417.170 through 417.180.

[45 FR 24353, Apr. 9, 1980, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.173 What are the requirements for an application?

(a) An applicant shall submit an application for a loan or loan guarantee to the Secretary at the time and in the form and manner that the Secretary prescribes.

(b) An application must contain an appraisal of the property to be acquired with a loan made or guaranteed under §§ 417.170 through 417.180. The appraisal must be prepared by an independent appraiser approved in advance by the Secretary.

(c)(1) An application must identify any party in interest (as defined in § 417.100 of this subpart) with whom a transaction is proposed and for which transaction assistance is being requested under §§ 417.170 through 417.180. The application must also identify any individual who would become a party in interest as a consequence of a proposed transaction.

(2) Where a party in interest is so identified, the application must include:

(i) An explanation of the involvement of the party in interest;

(ii) A combined financial statement for the HMO and the party in interest. This statement must be prepared by an independent auditor in accordance with generally accepted accounting principles with appropriate opinions and notes, and in the form and manner prescribed by the Secretary;

(iii) A second appraisal of property to be acquired from the party in interest. This second appraisal is in addition to that required under paragraph (b) of this section and must be prepared by another independent appraiser approved in advance by the Secretary;

(iv) Evidence that the cost of each proposed transaction with a party in interest is consistent with prudent management and the fiscal soundness requirements in § 417.107(a)(1); and

(v) Evidence that the transaction will not adversely affect the management decisions or the fiscal soundness of the HMO. For example, a description of procedures which will prevent the party in interest from controlling decisions by the HMO will respect to the facility to be constructed or acquired under §§ 417.170 through 417.180 would meet this requirement.

(3) The Secretary will disapprove an application where he or she determines that the participation of a party in interest is likely to affect adversely the administration and fiscal soundness of the HMO or its delivery of health services.

(d) An application must include an assurance satisfactory to the Secretary that the HMO will have title (as defined in § 417.171) to the facility.

(e) An application must include an assurance satisfactory to the Secretary that the HMO will continue to comply with the restrictions on capacity set out in § 417.176(b) for the five years following completion of acquisition or construction.

(f) An application must include line drawings of the proposed facility demonstrating that the allocation of square footage complies with the requirements of § 417.176.

(g) The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the regulations of this subpart, and the terms of the loan documents and the loan guarantee, if any.

EDITORIAL NOTE: Section 417.173 set forth below was published at 47 FR 19342, May 5, 1982. The effectiveness of § 417.173 is pending OMB review. A document will be published in the Federal Register announcing the results of OMB's review and the effective date of § 417.173 if approved. Section 417.173 set forth above remains in effect until further notice.

§ 417.173 What requirements must an applicant meet?

(a) An applicant shall provide an appraisal of the property to be acquired with a loan made or guaranteed under §§ 417.170 through 417.180. The appraisal must be prepared by an independent appraiser approved in advance by the Secretary.

(b)(1) An applicant shall identify any party in interest (as defined in § 417.100 of this subpart) with whom a transaction is proposed and for which transaction assistance is being requested under §§ 417.170 through 417.180. The applicant must also identify any individual who would become a party in interest as a consequence of a proposed transaction.

(2) Where a party in interest is so identified, the applicant shall provide:

(i) An explanation of the involvement of the party in interest;

(ii) A combined financial statement for the HMO and the party in interest. This statement must be examined by an independent auditor in accordance with generally accepted accounting principles with appropriate opinions and notes;

(iii) Evidence that the proposed transaction with a party in interest will be consistent with the requirements of §§ 417.100 through 417.109 of this subpart (for example, the fiscal soundness requirements in § 417.107(a)(1)).

(c) The applicant shall provide an assurance satisfactory to the Secretary that the HMO will have title (as defined in § 417.171) to the facility.

(d) The applicant shall include line drawings of the proposed facility demonstrating that the allocation of square footage complies with the requirements of § 417.176.

(e) The applicant shall provide assurances satisfactory to the Secretary that:

(1) At the time the application is made the HMO is fiscally sound;

(2) If the application is for a loan, the HMO is unable to secure a loan, at the rate of interest prevailing in the area in which the organization is located, from non-Federal lenders for the project with respect to which the application is submitted, or, if the application is for a loan guarantee, the HMO would be unable to secure a loan from such lenders for the project without the loan guarantee; and

(3) During the period of the loan or loan guarantee, the HMO will remain fiscally sound.

[47 FR 19342, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.174 What information must be submitted by an applicant which has received a commitment for a loan to be made or guaranteed under §§ 417.170 through 417.180 before the closing of the loan?

(a) Design, bid, and contract documents for each project must be prepared in accordance with all of Part 2.1 (except sections 5.4, 8.8, 11.2, 11.3, 11.4, Chapter 12, sections 13.2, 13.3 and Exhibits 9 and 10) of DHHS *Technical Handbook for Facilities Engineering and Construction Manual, Federally Assisted Construction*, entitled "2.1 Information for Project Applicants and State Agencies on Design and Construction Related Activities." With these exceptions, Part 2.1 is incorporated into §§ 417.170 through 417.180 by reference. This part of the Handbook will be provided to all applicants and is available at cost to any interested person upon request to the Office of Health Maintenance Organizations in any of the Department's Regional Offices. The addresses of Regional Offices are listed in 45 CFR 5.31(b). This part of the Handbook is also available for inspection without charge at these offices. If this handbook is amended, a notice of the amendments will be published in the FEDERAL REGISTER and a copy of the amendments will be on file at the Office of the Federal Register. The design, bid, and contract documents must be submitted to the Secretary for approval before the closing of a loan to be made or guaranteed under §§ 417.170 through 417.180.

(b) The plans and specifications for the design and construction of, and equipment for, a facility submitted to the Secretary must conform with:

(1) State and local codes, laws, and ordinances, and

(2) Chapter 14 of DHHS Publication No. (HRA) 79-14500, *Minimum Requirements of Construction and Equipment for Hospitals and Medical Facilities*, "Small Primary Health Care Centers," except for the last sentence of paragraph 14.1A, the parenthetical phrase "(usually 4)" in paragraph 14.1B(1) and paragraph 14.1B(3) in its entirety. With these three exceptions, Chapter 14 of this document is incorporated into §§ 417.170 through 417.180 by reference. This publication will be provided to all applicants and is available for the cost of reproduction to any interested person upon request to the Office of Health Maintenance Organizations in any of the Department's Regional Offices. The addresses of Regional Offices are listed in 45 CFR 5.31(b). This publication is also available for inspection without charge at these offices. If this publication is amended, a notice of the amendments will be published in the FEDERAL REGISTER and a copy of the amendments will be on file at the Office of the Federal Register.

§ 417.175 What are the limitations on loans and guaranteed loans?

(a) The aggregate amount of principal of loans made or guaranteed, or both, for an ambulatory health care facility under §§ 417.170 through 417.180 may not exceed the amount specified by section 1305A(c)(1) of the Public Health Service Act.

(b) The aggregate amount of loans made or guaranteed under §§ 417.170 through 417.180 for a project may not exceed 90 percent of the eligible costs of the project unless the Secretary, for good cause, approves a greater percentage.

(1) In determining whether there is good cause for approving a greater percentage, the Secretary will consider:

(i) The availability of other sources of funds to the applicant;

(ii) The effect on the security for the loan of other borrowing by the applicant to pay for the remainder of the project costs; and

(iii) Any other factors the Secretary determines are consistent with the purposes of the Public Health Service Act.

(2) The applicant may not use any funds provided under sections in this subpart other than §§ 417.170 through 417.180 to pay for the applicant's portion of eligible costs for a project assisted under §§ 417.170 through 417.180.

[45 FR 24353, Apr. 9, 1980, as amended at 47 FR 19342, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.176 What requirements apply to projects assisted under §§ 417.170 through 417.180?

Projects assisted or to be assisted under §§ 417.170 through 417.180 must comply with the following requirements, unless a requirement is waived or modified by the Secretary for good cause.

(a) *Net assignable square footage limitations applicable to a facility.* The following limitations apply to an assisted facility, including any portion of the facility acquired or constructed (or to be acquired or constructed prior to the termination of the 5-year period following acquisition or construction) without Federal assistance under §§ 417.170 through 417.180:

(1) Not more than 25 percent of the net assignable square footage (as defined in § 417.171) may be devoted to administrative functions of the HMO. The remainder must be devoted to clinical use. For the purpose of this paragraph, (i) administrative functions include general administration, marketing, enrollment and claims processing, and (ii) clinical uses of space include medical records storage, clinical administration, and space for the provision of basic health services, health education, and pharmacy, optical, dental, laboratory, X-ray, and other health services.

(2) At least 50 percent of the net assignable square footage must be for the provision of basic health services (as defined in §§ 417.100 through 417.109 of this subpart).

(b) *Net assignable square footage limitations applicable to an HMO.* The following limitations apply to the net assignable square footage of all the facilities to be available to the HMO during the five year period following the completion of the acquisition or construction to be assisted under §§ 417.170 through 417.180. This includes any net assignable square footage available or to be available to the HMO for the purposes specified below, whether or not acquired or constructed with assistance under §§ 417.170 through 417.180:

(1) The net assignable square footage available to the HMO may not exceed that needed to serve 110 percent of the projected number of HMO members at the end of the 5 year period after the acquisition or construction is to be completed. The applicant shall calculate the amount of net assignable square footage which is needed in accordance with instructions provided by the Secretary.

(2) Where assistance under §§ 417.170 through 417.180 is used to acquire or construct facilities for the provision of optical, pharmacy or dental services, the total net assignable square footage available to the HMO for the provision of each of these assisted services may not exceed that needed to serve 110 percent of the projected number of HMO members at the end of the five year period after the acquisition or construction is to be completed. Only the HMO members projected to be enrolled to receive these services on a prepaid basis may be counted for purposes of this limitation. The applicant shall calculate the amount of net assignable square footage which is needed in accordance

with instructions provided by the Secretary.

(3) Where assistance under §§ 417.170 through 417.180 is used to acquire or construct facilities for the provision of laboratory or X-ray services, the total net assignable square footage available to the HMO for the provision of each of these assisted services may not exceed that needed to serve 110 percent of the projected number of HMO members at the end of the 5 year period after the acquisition or construction is to be completed. The applicant shall calculate the amount of net assignable square footage which is needed in accordance with instructions provided by the Secretary.

[45 FR 24353, Apr. 9, 1980, as amended at 47 FR 19342, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.177 What is an eligible cost?

(a) The Secretary will consider only eligible costs in determining the amount of a loan to be made or guaranteed under §§ 417.170 through 417.180. Eligible costs are those which are reasonable and necessary for the acquisition or construction of, or the purchase of equipment for, a facility or portion of a facility. Costs which the Secretary determines to be inappropriate to the needs of a particular HMO and other costs which the Secretary specifies in materials to be provided to each applicant are not eligible costs.

(b) The cost of acquisition of equipment is an eligible cost only if the equipment is for a facility acquired or constructed, or to be acquired or constructed, with a loan made or guaranteed under §§ 417.170 through 417.180.

(c) Acquisition of land for a facility is an eligible cost only if it is in connection with the acquisition or construction of a facility on that land.

(d) The costs of leasing land, a facility, or equipment for a facility are not eligible costs. The costs of construction on leased land, including renovation of a leased facility, may be eligible costs if adequate security is available to protect the financial interests of the United States.

(e) The cost of repaying an interim construction loan for a facility is an eligible cost.

§ 417.178 What security is required?

(a) Each loan made by the Secretary shall bear interest at a rate comparable to the current rate prevailing, with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges. The Secretary may set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date the disbursement is made for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

(b) Each loan guaranteed by the Secretary shall bear interest at a rate the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for loans with similar maturities, terms, conditions, and security and the risks assumed by the United States.

[47 FR 19342, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.179 How and over what period are loans and guaranteed loans to be repaid?

(a) The principal amount of each loan or guaranteed loan, together with interest thereon, must be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan, or by the parties to the guaranteed loan and the Secretary, prior to or at the time of the closing of the loan. Unless otherwise authorized by the Secretary, each loan made or guaranteed by the Secretary must be repayable in substantially level installments of interest and principal (except as provided in paragraph (b) of this section) sufficient to amortize the loan through the final year of the life of the loan.

(b) Interest on the unpaid principal amount of the loan shall be due and payable not less frequently than semiannually from the date of the initial disbursement of funds under the loan. Principal repayments shall be paid not less frequently than semi-annually but may be deferred until completion of the project.

(c) Each loan or guaranteed loan shall be repayable over a period approved by the Secretary, not to exceed 25 years beginning on the date of closing of the loan.

(1) The Secretary may approve a repayment period of less than 25 years in particular cases if he or she determines that a shorter repayment period is more appropriate to an applicant's total financial plan and not inconsistent with the financial interests of the United States.

(2) A loan repayment period may not exceed the estimated useful life of the facility to be acquired or constructed with the assistance of the loan. In the case of a loan solely for acquisition of equipment for a facility previously assisted under §§ 417.170 through 417.180, the loan repayment period may not exceed the estimated useful life of the most expensive items of equipment.

(3) Where a leased facility is being constructed (i.e., renovated) with assistance under §§ 417.170 through 417.180, or a facility is being acquired or constructed on leased land with assistance under this subpart, the loan repayment period may not be longer than the period of the lease.

[45 FR 24353, Apr. 9, 1980. Redesignated at 47 FR 19342, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

§ 417.180 On what basis may the Secretary waive rights of recovery?

In determining whether there is good cause for waiver of any right of recovery which the Secretary may have against an HMO, either because of a loan made under §§ 417.170 through 417.180 or because of a payment made under a loan guarantee under §§ 417.170 through 417.180, he or she will take into consideration the extent to which:

(a) The recipient of the loan or guaranteed loan or other owner of the facility with respect to which the loan or loan guarantee was made will continue to use it for (1) the purpose for which it was constructed or (2) another public or nonprofit purpose which will promote the purposes of the Public Health Service Act;

(b) There are reasonable assurances that for the remainder of the repayment period of the loan, other public or nonprofit facilities not previously used for the purpose for which the facility was constructed will be so used and are substantially equivalent in nature and extent for that purpose;

(c) The recovery would seriously curtail the provision of medical services to persons in need of these services in the area; and

(d) It is likely that payment can be obtained which would be greater than the costs the government would incur as a result of continuing to pursue collection.

[45 FR 24353, Apr. 9, 1980. Redesignated at 47 FR 19342, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987]

Subpart B—Health Maintenance Organizations

Editorial Note: Nomenclature changes affecting Subpart B appear at 50 FR 1345, Jan. 10, 1985.

§ 417.201 Health maintenance organizations; general.

(a) *Introduction.* The regulations in this Subpart B set forth the requirements which an organization must meet in order to be eligible to enter into a contract with the Secretary as a health maintenance organization (HMO) under the health insurance program for the aged and disabled (title XVIII of the Social Security Act) and to be reimbursed through capitation payments for covered items or services the organization furnishes title XVIII beneficiaries who have enrolled with it. Any references in this subpart to functions being performed by HCFA may at HCFA's option be performed directly by HCFA or by contract.

(1) *HMO Amendments of 1976.* The requirements described in this subpart reflect the provisions of section 201 of Pub. L. 94-460 (the HMO Amendments of 1976) which amended section 1876 of the Social Security Act, to align the title XVIII definition of an HMO more closely with the definition of an HMO

under title XIII of the Public Health Service (PHS) Act. The 1976 amendments, however, preserved a number of statutory requirements which apply to any organization which wishes to participate as an HMO under title XVIII. These regulations include the PHS requirements that apply to an HMO under title XVIII. They are specified in § 417.203. The requirements which are unique to title XVIII are described in §§ 417.201(b), 417.204, 417.205, and 417.207, and include those dealing with types of HMO's, HMO membership (including an open-enrollment provision which is different from that applied under the PHS Act), range of services, method of reimbursement, and other requirements as specified.

(2) *General definition of a title XVIII HMO.* For title XVIII purposes, an HMO is defined as a legal entity which, except as provided by section 1876(b)(1) of the Social Security Act, provides health services on a prepayment basis to its enrolled members in a manner prescribed by section 1301(b) of the PHS Act (42 U.S.C. 300e), and is organized and operated in a manner prescribed by section 1301(c) of the PHS Act, and meets all other applicable requirements of section 1876 and this subpart.

(3) *Contract with the Secretary.* In order to participate and receive payment as an HMO under Medicare, an organization must enter into a contract with the Secretary as an HMO. The requirements pertaining to the Secretary's contract with an HMO are specified in §§ 417.228 through 417.239.

(b) *Other applicable regulations.* Subpart C of this part contains regulations and effective dates applicable to organizations qualifying for Medicare payments under section 1876 of the Act as amended by section 114 of Pub. L. 97-248 (Tax Equity and Fiscal Responsibility Act of 1982).

(c) *Types of title XVIII health maintenance organizations.* HMO's may be distinguished according to their level of development or method of Medicare (title XVIII) reimbursement.

(1) For purposes of this subpart, a "mature" HMO refers to an organization which meets the statutory definition of an HMO (see section 1876(b) of the Act) and is in full compliance with the qualifying conditions set forth in this subpart. Where a mature HMO also meets the requirements of paragraph (a)(1) or (a)(2) of § 417.204 which are applicable to the organization, it may elect to contract with the Secretary as either a "risk-basis" or a "cost-basis" HMO (as described in paragraph (b)(4) of this section). A mature HMO which does not meet the applicable requirements of paragraph (a)(1) or (a)(2) of § 417.204 can only contract with the Secretary on a cost basis.

(2) A "developing HMO" refers to an organization which does not fully meet the requirements applicable to a mature HMO. To qualify as a developing HMO, an organization must demonstrate to the Secretary that it has a reasonable prospect of fully meeting all the requirements for a mature HMO and it must have a planned program which is acceptable to the Secretary and to which it is committed for meeting all of the requirements for a mature HMO within 3 years after the effective date of its initial contract with the Secretary as an HMO under title XVIII. Periodic reviews are conducted by the Secretary or his designate to determine whether the developing HMO is accomplishing its planned program on schedule and, where the HMO has fallen behind schedule, the Secretary determines whether the HMO has made sufficient progress toward meeting the requirements of a mature HMO to warrant a renewal of its title XVIII contract. A developing HMO may contract with the Secretary only on a cost-basis.

(3) The Secretary may extend the period of time beyond the 3 years specified in paragraph (b)(2) of this section, for a developing HMO to qualify as a mature HMO:

(i) Where the HMO documents that it has made every effort to comply within three years of its initial contract as a developing HMO and that it is currently making sufficient progress in meeting applicable qualifying conditions and standards;

(ii) Where the HMO establishes a timetable for meeting the requirements, which is acceptable to the Secretary; and

(iii) Where the HMO meets such requirements as may be set forth by the Secretary for extension of the period of time beyond the three years specified in paragraph (b)(2) of this section.

(4) If a mature HMO, which is eligible to contract with the Secretary on a risk-basis, elects to do so, it shall share with the health insurance program a portion of the savings which accrue where it provides services to its enrollees who are title XVIII beneficiaries at a cost lower than the adjusted average per capital cost, as defined in section 1876(a)(3)(A) of the Act and in this subpart. Savings up to 20 percent of the adjusted average per capita cost shall be apportioned equally between the risk-basis HMO and the Federal Hospital Insurance Trust Fund and/or the Federal Supplementary Medical Insurance Trust Fund. Savings in excess of 20 percent of the adjusted average per capita cost shall be apportioned entirely to such trust funds. Losses incurred by the risk-basis HMO shall be absorbed by such organization, but losses shall be carried forward and offset from savings realized in later years. An organization, either mature or developing, which enters into a cost-basis contract with the Secretary is reimbursed the reasonable cost it incurs in providing covered items and services to its title XVIII beneficiaries.

[40 FR 28018, July 2, 1975; 40 FR 29706, July 15, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 5826, Feb. 10, 1978; 44 FR 29061, May 18, 1979; 49 FR 3659, Jan. 30, 1984; 49 FR 36103, Sept. 14, 1984. Redesignated and amended at 50 FR 1345, Jan. 10, 1985]

§ 417.202 Qualifying conditions: General.

An HMO which wishes to contract with the Secretary pursuant to section 1876 of the Act must be able to demonstrate its ability to provide to its enrollees who are title XVIII beneficiaries, a specified range of comprehensive services efficiently, effectively, and economically. An assessment of an organization's ability to meet the definitional requirements of an HMO under title XVIII of the Act as defined in section 1876 is necessarily based on the organization's ability to enroll members and deliver high quality health services. The qualifying conditions specified in §§ 417.203 through 417.205 and 417.207 are designed to assure the Secretary or his delegate of the HMO's ability to fulfill these requirements as provided by section 1876 of the Act. Generally, each qualifying condition is interpreted by a series of standards. Reference to these standards is made by the Secretary when surveying an HMO to document its activities, to establish the nature and extent of its deficiencies, if any, and if the Secretary enters into a contract with the HMO, to assess the HMO's need for improvement in relation to the prescribed qualifying conditions. The application of the standard indicates the extent and degree to which an applicant organization is complying with each condition. To qualify as an HMO under title XVIII of the Act, a mature HMO must be in compliance with all of the qualifying conditions and applicable standards set forth in §§ 417.203 through 417.205 and 417.207. A developing HMO in order to qualify as an HMO under title XVIII of the Act must be in compliance with all of the qualifying conditions and standards set forth in §§ 417.203 through 417.205 and 417.207 except for the standards specified in §§ 417.204(a) and 417.205(a), and must demonstrate that it is making reasonable efforts, as described in § 417.201(b)(2), to meet fully the standards in §§ 417.204(a) and 417.205(a).

[43 FR 5826, Feb. 10, 1978. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.203 Qualifying conditions: Public Health Service Act requirements.

An HMO must demonstrate that, except as provided by section 1876(b)(1) of the Social Security Act, it meets the applicable requirements of section 1301(b) and section 1301(c) of the PHS Act and applicable regulations (see 42 CFR Part 110 on Health Maintenance Organizations). In complying with this condition, an HMO must meet the PHS regulatory requirements in 42 CFR 110.101 (i) or (j); 110.104(a) (1), (2), and (3);

110.105(a) (1) and (2); 110.106(a); 110.107; 110.108 (a) and (c); and 110.108 (f) through (r).

[43 FR 5827, Feb. 10, 1978. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.204 Qualifying condition: Membership.

The HMO must demonstrate that it has operating experience and an enrolled population sufficient to provide a reasonable basis for establishing a prospective per capita reimbursement rate.

(a) *Standard: Operating experience for mature HMO's.* To be eligible to contract as a mature HMO, the organization must have a current enrollment of at least 5,000 members on a prepaid capitation basis. In order to be eligible to contract as a risk-basis HMO (see § 417.201(b)), the requirements regarding operating experience in paragraph (a)(1) or (a)(2) of this section apply:

(1) The organization must have a current enrollment of at least 25,000 members on a prepaid capitation basis, and must have been the primary source of health care for at least the range of health care services described in § 417.205(b) which were provided to at least 8,000 persons in each of the 2 years immediately preceding the contract year in which it first qualifies as a risk-basis HMO.

(2) Where the organization serves a non-urban geographic area, and has a current enrollment of at least 5,000 members on a prepaid capitation basis, it need not meet the requirements in paragraph (a)(1) of this section if it has provided at least the range of health care services referred to in § 417.205(b) to at least 1,500 persons in each of the 3 years immediately preceding the contract year in which it first qualifies as a risk-basis HMO. For purposes of this section, a non-urban HMO is an organization:

(i) Whose service area is located in a non-metropolitan county (i.e., a county with fewer than 50,000 inhabitants); or

(ii) Whose normal service area includes at least one such county or

(iii) Whose service area is located outside a metropolitan area and whose facilities are within reasonable travel distance of fewer than 50,000 people. In assessing what is a reasonable travel distance primary consideration will be given to the actual availability of services and general community standards in securing health services.

(3) Where an organization is a subdivision or subsidiary of a mature HMO which meets the requirements of paragraph (a)(1) or (a)(2) of this section, such subdivision or subsidiary need not demonstrate that it meets such requirements as an independent unit if the mature organization assumes responsibility for the financial risk and adequate management and supervision of health care services rendered by such a subsidiary. Also, two or more independent organizations may combine through merger or effective affiliation arrangements in order to satisfy the minimum enrollment standard specified in paragraph (a)(1) or (a)(2) of this section.

(b) *Standard: Operating experience for developing HMO's.* To contract as a developing HMO (see § 417.201(b)), the organization must provide at least the range of services referred to in § 417.205(b) on a prepaid capitation rate basis to a sufficient number of individuals to assure the Secretary that there is a reasonable basis for determining a prospective per capita rate of reimbursement or have some other method acceptable to the Secretary of providing a sound basis for making proper cost projections.

(c) *Standard: Composition of enrollment.* In addition to meeting the requirements of paragraph (a) or (b) of this section, HMO's, whether mature or developing, must meet the following standards with respect to the composition of their enrollment:

(1) At least 50 percent of the HMO's membership must be under age 65. However, this requirement may be waived by the Secretary where:

(i) The requirement would result in enrollment of enrollees substantially nonrepresentative of the population in the geographic area served by such HMO, or

(ii) The organization presents a plan which satisfies the Secretary that it will meet this requirement within 3 years after it enters into its initial contract with the Secretary and the HMO demonstrates each year that it is making continuous efforts and progress towards achieving compliance with the requirement within such three-year period by holding open enrollment periods and taking other steps as necessary.

(2) No more than 50 percent of the organization's members may be beneficiaries (or recipients) of the health benefit programs established by titles XVIII and XIX of the Act; however, this requirement may be waived by the Secretary where:

(i) The organization presents a plan which satisfies the Secretary that it will meet such requirements within 3 years after it enters into its initial contract with the Secretary and the HMO demonstrates each year that it is making continuous efforts and progress toward achieving compliance with this requirement within such 3-year period by holding open-enrollment periods and taking other steps, as necessary; or

(ii) Beneficiaries of such programs comprise more than fifty percent of the population of the geographic area served by the organization and the HMO's enrollment of such beneficiaries is not substantially nonrepresentative of the concentration of such beneficiaries in such geographic area; or

(iii) The organization otherwise shows good cause for a waiver of this requirement.

(d) *Standard: Open enrollment.* An HMO will enroll title XVIII beneficiaries on a first-come, first-served basis, up to the limit of its capacity, and will hold an open enrollment period not less than annually for such beneficiaries on that basis. This requirement may be waived by the Secretary where the organization's compliance would result in a failure to meet the requirements of § 417.204(c)(1) or would result in a membership which is substantially nonrepresentative of the population in the area it serves. For purposes of this subpart, a subgroup of enrollees is generally not considered to make the membership substantially nonrepresentative unless its proportion among all the HMO's enrollees exceeds by at least 10 percentage points its proportion in the general population in the same enrollment area (see § 417.205(a)(1)), based on such census and other data as the Secretary finds appropriate.

[40 FR 28018, July 2, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 5827, Feb. 10, 1978. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.205 Qualifying condition: Range of services.

(a) *Standard: Range of services provided by mature HMO's.* The mature HMO (see § 417.201(b)) must provide a comprehensive range of services which meets the following criteria as to scope and area;

(1) (i) The mature HMO must provide to its enrollees who are title XVIII beneficiaries, directly or through arrangements with others (see 42 CFR 110.104), basic health services which, for purposes of this subpart, means all of the items and services covered under the health insurance program (see Subparts A and B of Part 405 of this chapter) which are available to individuals who are not enrolled in the HMO (non-enrollees) residing in the HMO's service area. (See 42 CFR 110.101(d).) In its service area, the organization must offer its full range of covered title XVIII items or services to its enrollees who are title XVIII beneficiaries. The HMO's service area is different from an HMO's enrollment area (i.e., the geographic area encompassing the permanent residences of its enrollees) which may include locations outside the organization's service area where it offers less than its full range of covered title XVIII items or services.

(ii) The Secretary shall determine whether a service is available to individuals residing in an HMO's service area on the basis of all relevant facts, including:

(A) Whether part or all of the HMO's service area has been designated as a medically underserved area; or

(B) Whether the Secretary has otherwise determined that there is in the service area a scarcity of covered items and services or qualified personnel to provide them.

(iii) A "medically underserved area" for purposes of this subpart is an urban or nonurban geographic area designated by the Secretary as an area with a shortage of one or more basic types of health services, e.g., physicians' services and inpatient hospital services. (Designations with respect to such urban or nonurban areas are made by the Secretary as described in 42 CFR 110.203(g).)

(2) Even though a particular item or service covered under the health insurance program is not available from physicians, suppliers, or providers of services which are located in the HMO's service area, the organization must be responsible for arranging and paying for those covered items or services if patients in its service area (other than enrollees of the organization) are commonly referred for those services, when needed, to sources outside the area.

(3) The mature HMO must, except as provided for in paragraph (a)(4) of this section, also assume financial responsibility and provide reasonable reimbursement for all medically necessary covered items and services obtained by its enrollees from physicians, suppliers, or providers of services outside the HMO, even in the absence of the organization's prior approval, where such services are:

(i) Emergency services: Emergency services, for purposes of this subpart, are covered inpatient or outpatient medical and other services provided by an appropriate source within or outside the HMO's service area, which may not be delayed until facilities or suppliers of services of the HMO (or alternatives authorized by the HMO) can be used without possible serious effects on the health of the patient. Such services must be or must appear to be needed immediately to prevent the death of the enrollee or serious impairment of his health, and are considered emergency services as long as the transfer of the enrollee to the appropriate provider of services of the HMO (including those with which the HMO has an arrangement) or an alternative designated by the HMO is precluded because of the risk to the enrollee's health, or the distance and nature of illness involved would make such transfer unreasonable;

(ii) Urgently needed services: Urgently needed services are covered services which enrollees require in order to prevent a serious deterioration in their health while they are temporarily absent from the HMO's service area. While the immediacy of need for these services is not as great as it is for emergency services, the medical need is such, however, that the provision of medical services cannot be delayed until the enrollee returns to a place where he would reach the HMO's services. In this context, the term "temporarily absent," refers to circumstances, such as a vacation trip, where the enrollee has left the health maintenance organization's service area, but intends to return within a reasonable period of time. An enrollee whose primary place of residence is in either the HMO's service area or enrollment area, but who resides in a temporary home elsewhere for a number of weeks up to a reasonable limit that may be established by the HMO, would also be considered temporarily absent from the HMO's service area during those periods of time when such an enrollee is residing in the temporary home; or

(iii) Services which are found upon appeal by the beneficiary under the provisions of section 1876(f) of the Act (42 U.S.C. 1395mm(f)) to be services which the beneficiary was entitled to have furnished to him by such HMO.

(4) A mature health maintenance organization (see § 417.201(b)) which either is not eligible to be paid on a risk-basis because it does not meet the requirements regarding operating experience set forth in paragraph (a)(1) or (a)(2) of § 417.204, or is eligible for risk-basis payment but elects to be paid on a cost-basis, is not required to assume financial responsibility for any services its enrollees who are title XVIII beneficiaries receive which are:

(i) Emergency services (see paragraph (a)(3)(i) of this section) or

(ii) Urgently needed services (see paragraph (a)(3)(ii) of this section) or other covered items or services received outside the HMO's service area by its enrollees who are title XVIII beneficiaries (but not including those described in paragraph (a)(2) of this section). Covered items or services which the beneficiary receives from physicians, suppliers, or providers of services outside the HMO and for which the HMO does not assume financial responsibility are reimbursable under the regular health insurance program.

(5) In providing items and services where more than one category of practitioner is qualified to provide the item or service, the health maintenance organization may select the type of practitioner to be used.

(b) *Standard: Range of services provided by developing HMO's.* A developing HMO must provide at least the following services to its enrollees who are title XVIII beneficiaries: Inpatient hospital services; physicians' services; diagnostic X-ray, laboratory and other diagnostic tests; and ambulance services. A contract with a developing HMO is renewed only if the Secretary finds that it is making reasonable efforts to provide all covered items and services available in its service area (see § 417.201(b)).

[40 FR 28018, July 2, 1975; 40 FR 29706, July 15, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 5827, Feb. 10, 1978. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.207 Qualifying condition: Provision of services.

An HMO must provide the services and benefits required in § 417.205 to its enrollees who are insured for benefits under the hospital insurance and supplementary medical insurance programs of title XVIII, or for benefits under the supplementary medical insurance program alone, through institutions, entities, and persons meeting the applicable requirements of section 1861 of the Social Security Act, as amended (42 U.S.C. 1395x).

(a) *Standard: Conformance with title XVIII conditions of participation and conditions for coverage.* If title XVIII covered items or services are provided by a hospital, skilled nursing facility, home health agency, or a provider of outpatient physical therapy or speech pathology services, such provider of services must meet the applicable conditions of participation as described in Subparts K, L, and Q of this part and Part 482 of this chapter. Similarly, if services are provided by independent laboratories or portable X-ray suppliers, or suppliers of end-stage renal disease or kidney transplantation services, those laboratories or suppliers must meet the applicable conditions for coverage, as set forth in Subparts M, N, and U of Part 405 of this chapter.

(b) *Standard: Physician supervision.* The HMO's health delivery system must provide for supervision by a physician as prescribed in section 1861 of the Social Security Act (42 U.S.C. 1395x) of other health care professionals who are directly involved in the provision of health care.

(1) In the case of services furnished by the HMO's clinics (or its arranged-for physician offices), the HMO must demonstrate to the satisfaction of the Secretary or his delegate that:

(i) Services by other health care professionals are under the direct supervision of a physician, and

(ii) A physician (or physicians) is present to perform medical (rather than administrative) services at all times that the HMO's clinics (or its arranged-for physician offices) are open, and

(iii) Each patient is under the care of an HMO physician (or HMO arranged-for physician).

(2) For purposes of this subpart, the term "other health care professionals" refers to those paramedical, ancillary, and other nonphysician personnel who are engaged in the delivery of health services.

[43 FR 5827, Feb. 10, 1978. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 22041, June 17, 1986]

§ 417.220 HMO enrollment.

(a) *General.* An individual may elect to receive through an HMO, services that are covered under the hospital insurance program and supplementary medical insurance program if he is entitled under both programs, or under the supplementary medical insurance program if he is entitled only under that program. He may receive such services through an HMO by enrolling in an HMO that has contracted with the Secretary (see §§ 417.202–417.207 for the qualifying conditions which HMO's must meet and paragraph (b) of this section for the requirements to be met by prospective enrollees). Payments for health insurance program beneficiaries who have enrolled in such an HMO will be made out of the Federal Hospital Insurance Trust Fund and/or the Federal Supplementary Medical Insurance Trust Fund, as appropriate. Such payments will be made to the HMO on behalf of such individuals, and will discharge such individuals from the liability to pay for the covered services furnished to them by the HMO. The HMO may require payment, in the form of premiums or otherwise, from such individuals for services not covered under the health insurance programs, as well as deductibles and coinsurance amounts attributable to covered services (see § 417.222(b)). Enrollees of HMO's which have entered into a risk-basis contract with the Secretary are also liable for services received from sources other than the HMO, unless covered through the HMO pursuant to this subpart (see §§ 417.221 (a) and (b) and 417.222(c)).

(b) *Eligibility to enroll in an HMO.* An HMO shall enroll, either on an indefinite basis or for a specified length of time, but not less than 12 months, any individual:

(1) Who is enrolled in the supplementary medical insurance program and is entitled to benefits under the hospital insurance program or is enrolled in the supplementary medical insurance program only;

(2) Who lives within the HMO's service area (see § 417.205(a)) or a location outside its service area that is within its enrollment area (see § 417.205(a)) in which the services the HMO is required to furnish health insurance program beneficiaries pursuant to § 417.205(a)(1) or (b), as the case may be, are available to the beneficiary through the HMO;

(3) Who is not enrolled pursuant to this subpart in any other HMO which has entered into a contract with the Secretary;

(4) Who, during an enrollment period of the HMO, completes and signs the application form used by such organization to enroll members and gives such information as may be required for enrollment;

(5) Who agrees to abide by the rules of the HMO after such rules are disclosed to the beneficiary in connection with the enrollment process;

(6) Who is not denied enrollment by the HMO (pursuant to the HMO's written selection policy, which has been approved by the Secretary in accordance with paragraph (c) of this section);

(7) Whose acceptance would not (i) cause the number of the HMO's members who are age 65 or older to exceed 50 percent of its enrolled members, or (ii) result in the HMO's failure to comply with any other qualifying condition set forth in §§ 417.202–417.207, or (iii) require such HMO to exceed its enrollment capacity (see § 417.223(b)).

(c) *Selection policies.* (1) An HMO's selection policies with respect to health insurance program beneficiaries will be approved by the Secretary only

(i) If the HMO has demonstrated to the satisfaction of the Secretary that applicants for enrollment who meet the requirements in paragraph (b)(1) through (5) of this section are rejected solely to prevent its membership from becoming substantially nonrepresentative of the population in its enrollment area; or

(ii) If the HMO can demonstrate, that enrollment of an individual or individuals otherwise eligible to enroll would cause it to be unable to provide needed health services to its enrollees; or

(iii) If the HMO has demonstrated to the satisfaction of the Secretary that it would be compelled to enroll a number of individuals which would exceed its capacity or cause it to otherwise not be able to comply with the requirements of paragraph (b) of this section; or

(iv) In the case of a risk-basis HMO (see § 417.201(b)), if such an HMO has demonstrated to the satisfaction of the Secretary by means of statistical and actuarial data, including pertinent financial and enrollment information, that otherwise it would be compelled to enroll an individual or individuals who would pose an immediate threat to the HMO's financial viability.

(2) Where a risk-basis HMO employs a selection policy which rejects indi-

viduals who would pose an immediate threat to the HMO's financial viability (see paragraph (c)(1)(iv) of this section), it must seek approval by the Secretary in advance and approval, if granted, shall be for a period not to exceed one full contract year. Approval for subsequent contract years may also be made, subject to renewed demonstration by the risk-basis HMO of the continued necessity for such a selection policy.

(3) A subgroup of enrollees will generally not be considered to make the membership substantially nonrepresentative unless its proportion among all the HMO's enrollees exceeds by at least 10 percentage points its proportion in the general population in the enrollment area, based on such census and other data as the Secretary finds appropriate. The HMO may accept enrollment from a particular group that exceeds its proportion in the population by more than 10 percentage points provided that such enrollment permits its enrollment of health insurance program beneficiaries in numbers sufficient to meet the requirements of § 417.204.

(d) *Conversion of HMO enrollees newly entitled to health insurance program benefits.* (1) (i) The HMO must accept as an enrollee any beneficiary who was an enrolled member of the HMO as of the month immediately before the month in which such beneficiary (*a*) attained age 65, or (*b*) became entitled to health insurance program benefits on the basis of chronic renal disease, or (*c*) became entitled to his 25th monthly disability benefit.

(ii) While such a beneficiary must sign an application form containing the information required pursuant to § 417.223(f)(1), unless § 417.225 applies the HMO must continue his enrollment. (See also paragraph (e) of this section and § 417.223(e)(2).)

(2) The HMO must make every effort to forward the information required pursuant to § 417.223(f)(1) for such an individual to the Social Security Administration (i) at least 90 days prior to such individual's attainment of age 65 or such individual's 25th month of entitlement to disability benefits, or, (ii) in the case of those individuals requiring treatment for end-stage renal disease, within 30 days immediately following the initiation of a course of renal dialysis, or on or before the day on which the individual enters a hospital in preparation for, and in anticipation of, a kidney transplant.

(e) *Reenrollment.* Where an HMO requires periodic reenrollment, it must reenroll health insurance program beneficiaries, unless disenrollment is warranted pursuant to the provisions of § 417.225.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 12535, Mar. 25, 1983. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.221 Health insurance program beneficiary's entitlement to items and services.

(a) *Individual entitled to benefits under the hospital insurance program and the supplementary medical insurance program*—(1) *Entitlement to items and services.* An individual who is entitled to benefits under the hospital insurance program and the supplementary medical insurance program and who is enrolled in an HMO with which the Secretary has entered into a contract pursuant to section 1876(i) of the Act, as amended, shall, subject to the conditions, exclusions, and limitations described in this part, be entitled to receive through the HMO all items and services, under both Parts A and B of title XVIII of the Act, which the individual needs and which are provided by such organization, either directly or through arrangements with others, for any month for which a per capita payment is made under the hospital insurance program and the supplementary medical insurance program, or any month for which he was entitled to have such a payment made to the HMO, in accordance with the requirements of this subpart.

(2) *Entitlement to reasonable payment.* Such an individual shall also be entitled to have reasonable payment timely made by an HMO to him or on his behalf, for title XVIII items and services he obtains from a physician, supplier, or provider of services outside the HMO where such benefits are

(i) Emergency items and services (as defined in § 417.205(a)(3)(i)) or urgently-needed services (as defined in § 417.205(a)(3)(ii)) for which the HMO has assumed financial responsibility; or

(ii) Covered items and services which, in accordance with section 1876(f) of the Act, it is determined that the beneficiary was entitled to have furnished to him.

(b) *Beneficiary is enrolled in the supplementary medical insurance program but is not entitled to benefits under the hospital insurance program.* An individual who is enrolled in the supplementary medical insurance program, but is not entitled to benefits under the hospital insurance program, and is enrolled in an HMO with which the Secretary has entered into a contract pursuant to section 1876(i) of the Act, shall be entitled to receive, and have payment made for, benefits as provided for in paragraph (a) of this section, but only with respect to items and services which are covered under the supplementary medical insurance program (as specified in Part 410 of this chapter).

(c) *Effective date of coverage.* (1) The liability of the health insurance program to make per capita payments to the HMO on behalf of the beneficiary shall begin with the first day of the month in which he is a member of the HMO, and he is entitled to health insurance program benefits as shown on the records of the Social Security Administration. In no case will such month be earlier than the month immediately following, or later than the third month following, the month in which the information regarding the beneficiary, required pursuant to § 417.223(f)(1) is received in acceptable form by the Social Security Administration, except where one of the following is met:

(i) The Secretary approves a later month which has been requested by the HMO and the beneficiary.

(ii) An individual enrolls in the supplementary medical insurance program pursuant to § 405.212 but applies to an HMO prior to the month in which he is to become entitled to benefits under the supplementary medical insurance program, or is a member of the HMO prior to his entitlement to health insurance program benefits (see § 417.220(d)). In that event, the effective month of membership as an enrollee of the HMO and health insurance program beneficiary shall, except as otherwise provided in this paragraph, be the first month for which he becomes entitled to benefits under the supplementary medical insurance program.

(2) The Health Care Financing Administration shall promptly advise the HMO of the month for which the liability of the health insurance program becomes effective for each health insurance program beneficiary who is added to its records as an enrollee of the HMO.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 41351, Nov. 14, 1986]

§ 417.222 Liability of a health insurance program beneficiary enrolled in an HMO.

(a) *Items and Services not covered under the hospital insurance program or the supplementary medical insurance program.* (1) The enrollee is liable for payment for all items and services not covered under the hospital insurance program and the supplementary medical insurance program. Where the enrollee is entitled to benefits under only the supplementary medical insurance program, he is liable for payment for all items and services covered under the hospital insurance program, as well as for items and services not covered under the supplementary medical insurance program. The HMO may offer to its enrollees who are health insurance program beneficiaries, coverage of such items and services as part of a supplemental benefit plan. Coverage of such items and services (excluding deductible and coinsurance amounts required under paragraph (b) of this section) under such supplemental benefit plans must be optional for health insurance program beneficiaries.

(2) If the supplemental plan premium includes charges for items and services in addition to all or part of the deductible and coinsurance

amounts, the portions of the premium amount applicable to deductible and coinsurance amounts must be computed separately from the charges for other items and services, and the amounts so computed must be disclosed to the beneficiary prior to the beneficiary's selection of coverage options and application for membership.

(3) The HMO must give written notice to all enrollees who are health insurance program beneficiaries of any proposed change in supplemental benefit plan premium rates at least 30 days prior to the effective date of such change.

(b) *Deductibles and coinsurance for covered HMO items and services.* The enrollee, or someone representing the enrollee, shall be generally responsible for satisfying the deductible and coinsurance amounts applicable to items and services covered under the hospital insurance program as described in Subpart G of Part 409 of this chapter and the supplementary medical insurance program, as described in Subpart E of Part 410 of this chapter. (Where enrollees are eligible, payment for noncovered services, deductibles, and coinsurance may be satisfied under the provisions of section 1843 of the Act.) The requirements for deductibles and coinsurance shall be satisfied by payment to the HMO by the enrollee, or by someone on his behalf such as under a State buy-in agreement, of equivalent amounts which do not exceed the actuarial value of the deductible and coinsurance for which its enrollees who are health insurance program beneficiaries otherwise would have been liable had they not enrolled in an HMO. The payment of such amounts may be made as a premium, membership fee, charge per unit, or similar charge (or as a portion thereof where such a charge represents prepayment for noncovered services).

(c) *Special rules regarding liability of enrollees of risk-basis HMO's.* (1) Except as otherwise provided in paragraph (c)(2) of this section, a health insurance program beneficiary who enrolls in an HMO which has entered into a risk-basis contract with the Secretary (see § 417.201(b)(3) may not have payments made to him or on his behalf by the health insurance program for any services he receives, which are not provided directly or through arrangements by the risk-basis HMO, except for services described in § 417.221(a)(2). This restriction shall cease to apply to a beneficiary who is disenrolled from a risk-basis HMO pursuant to § 417.225, effective with the month in which the liability of the health insurance program to make monthly capitation payments to the HMO in his behalf ceases, except that where the beneficiary moves out of the HMO's enrollment area, such restriction shall cease to apply effective with the month immediately following the month in which he moves.

(2) A health insurance program beneficiary who, prior to July 1, 1973, was enrolled in an HMO which has entered into a risk-basis contract with the Secretary, and who would otherwise be subject to the restriction set forth in paragraph (c)(1) of this section may elect to be exempted from such restriction, but only with respect to items and services which are furnished prior to July 1, 1976.

(3) Health insurance program beneficiaries who are enrolled in cost-basis HMO's (see § 417.201(b) (2) and (3)) are exempt from the restriction set forth in paragraph (c)(1) of this section.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 41351, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

§ 417.223 Enrollment procedures.

(a) *Open enrollment period required.* (1) An HMO shall hold an open enrollment period at least once during its contract year. During such open enrollment period an HMO will enroll health insurance program beneficiaries who meet the eligibility requirements of § 417.220(b) in the order in which their applications are received until such HMO is enrolled to the limits of its capacity, as defined in paragraph (b) of this section.

(2) The open enrollment period must be no less than 30 consecutive days. Continuously open enrollment throughout the year shall satisfy this requirement.

(b) *Enrollment capacity.* (1) The HMO's capacity to accept new enrollees shall be determined on the basis of the HMO's annual enrollment forecast, together with any adjustments based on the expansion of the HMO's facilities or staff since the forecast was made. The annual enrollment forecast should, to the extent feasible, reflect:

(i) A reasonable relationship between the total number of anticipated enrollees, their anticipated health needs, and the HMO's anticipated ability to provide the required health services;

(ii) Anticipated number of individual enrollments and group enrollments;

(iii) Actual or anticipated expansion of the ability to provide health services, such as increases in staff and facilities;

(iv) Other reasonable and relevant factors such as the HMO's past enrollment experience.

(2) The enrollment forecast shall be submitted to the Health Care Financing Administration no later than 90 days before the beginning of each contract year and in such form as the Health Care Financing Administration shall prescribe. The HMO shall promptly notify the Health Care Financing Administration in writing, of any changes in its capacity.

(3) Subject to the approval of the Secretary, the HMO may set aside a reasonable number of vacancies during a contract year to take care of contemplated needs from a group contract provided that the enrollment period under such group contract is to take place during the contract year and that any such vacancies which are set aside and are not filled within a reasonable period of time following the commencement of the enrollment period for the group contract are made available to health insurance program beneficiaries as well as other nongroup applicants pursuant to the requirements of this subpart.

(c) *Required marketing activities.* In offering its plan to health insurance program beneficiaries, the HMO shall:

(1) Provide health insurance program beneficiaries who express interest in applying for membership with the HMO's rules and regulations regarding membership and an adequate written description of:

(i) The HMO's basic benefit package for health insurance program beneficiaries and any supplemental benefit packages that are available, including the amounts of the premiums, if any, for such benefit packages;

(ii) The liability of an enrollee who is a health insurance program beneficiary, for deductible and coinsurance amounts, noncovered services, and out-of-plan services;

(iii) Enrollment eligibility and procedures; and

(iv) Such other information including hours of operation, clinic locations, and directions for obtaining service, as may be necessary in order for the beneficiary to make an informed decision on whether to enroll in the HMO;

(2) Submit all brochures, applications, and promotional and informational material which deal with enrollment of health insurance program beneficiaries with the HMO, to the Health Care Financing Administration for approval prior to issuance; (The HMO shall be notified, within 30 days of the receipt of such materials by the Health Care Financing Administration, as to whether they have been approved or disapproved by the Health Care Financing Administration.); and

(3) Notify the general public of its enrollment periods, whether they are for a limited duration or continuous, in an appropriate manner in appropriate media throughout its enrollment area.

(d) *Proscribed marketing activities.* The HMO may not engage in any of the following activities in marketing its plan to health insurance program beneficiaries:

(1) Practices which are discriminatory or unethical in nature;

(2) Activities which would mislead, misinform, confuse, or defraud health insurance program beneficiaries, or misrepresent the HMO, its marketing representatives, or the Health Care Financing Administration, such as claims that the HMO is recommended or endorsed by the Health Care Financing Administration (other than that the organization is approved as an HMO for purposes of participation in the health insurance program, and

that the organization is qualified as an HMO under the Health Maintenance Organization Act of 1973 (Pub. L. 93-222) or under title XIX of the Social Security Act, where appropriate), or claims that the Health Care Financing Administration recommends that the beneficiary enroll in the HMO or deceptive door-to-door solicitation;

(3) Offers of gifts or payment as an inducement to enroll in the HMO (this does not proscribe the explanation of any legitimate benefits the beneficiary might obtain as an HMO enrollee, such as eligibility to enroll in a supplemental benefit plan which covers such items as deductibles and coinsurance, preventive services, etc.); and

(4) Promises, claims, or other statements, written or oral, which conflict with, materially alter, or erroneously expand upon the information contained in the marketing materials approved by the Secretary.

(e) *Application system.* The HMO shall have an effective system for receiving, controlling, and processing applications for membership from health insurance program beneficiaries under which:

(1) Each beneficiary (whether previously a member of the organization or not) who wishes to enroll in the HMO signs an application form, dated at the time the HMO receives the application from the beneficiary.

(2) Applications from beneficiaries are accepted in chronological order by date of application (except as provided in § 417.220(d)), subject to restrictions permitted by § 417.220(c). The date of application is the date on which the HMO receives the application from the beneficiary.

(3) The beneficiary is notified by the HMO of its acceptance or denial of his application:

(i) Not later than 30 days following the application date; or (ii) more than 30 days, and less than 61 days, following the application date if such HMO demonstrates to the satisfaction of the Secretary that more than 30 days is required for such purpose and is given approval by the Secretary to notify such beneficiary later than 30 days.

(4) Such notice is made as follows:

(i) If the application is accepted, the beneficiary is notified of the date upon which the HMO will request that his enrollment be effective, or

(ii) If the application is accepted, but the HMO is enrolled to capacity, the beneficiary is notified of procedures to be followed as vacancies occur, or

(iii) If the application is denied, an explanation of the reason for denial is given to the beneficiary.

(5) The HMO transmits to the Social Security Administration the information necessary to add the beneficiary to the HMO on the Social Security Administration's records:

(i) Within 30 days of the date of application or (ii) in the case of applications which are accepted when the HMO is enrolled to capacity, within 30 days after a vacancy for the applicant has occurred; or (iii) where the HMO demonstrates to the satisfaction of the Secretary that it requires more than 30 days to process and transmit the necessary information to the Social Security Administration, within such additional period of time which the Secretary grants for such purpose.

(6) The beneficiary is promptly informed in writing by the HMO of the effective month of his membership as an enrollee and a health insurance program beneficiary following notice to the HMO by the Health Care Financing Administration pursuant to § 417.221(c)(2).

(7) If the HMO accepts applications when it is filled to capacity, its procedures for processing and controlling such applications from health insurance program beneficiaries assure that vacancies that occur for such applicants who are still eligible to enroll are filled in chronological order by date of application, except where to do so would result in the HMO's failure to comply with the qualifying conditions set forth in §§ 417.202 to 417.207.

(f) *Application form.* (1) The application form must be in such format and contain such information as the Health Care Financing Administration may specify, including the beneficiary's authorization for disclosure and exchange of necessary information between the HMO and the Health Care Financing Administration.

(2) Application forms shall be filed and retained as long as the Secretary may prescribe.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.224 Membership rules.

(a) The HMO shall maintain written rules regarding membership which are reasonable and which do not conflict with the requirements and limitations imposed by this subpart. Such rules and regulations shall deal with, but need not be limited to, procedures for paying premiums and other charges for which enrollees who are health insurance program beneficiaries may be liable, grievance and appeal procedures, disenrollment rights, how and where to obtain services from or through the HMO, and such other matters as the Secretary may prescribe.

(b) A copy of such written membership rules shall be furnished each enrollee who is a health insurance program beneficiary (see § 417.223(c)(1)).

(c) Any change in the membership rules affecting enrollees who are health insurance program beneficiaries must first be approved by the Health Care Financing Administration and must be communicated in writing to all such enrollees of the HMO no later than 30 days prior to the effective date of the change. The HMO shall be notified, within 30 days of the receipt of such proposed change(s) by the Health Care Financing Administration, as to whether the change(s) has been approved or disapproved by the Health Care Financing Administration.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.225 Disenrollment.

(a) *HMO disenrollment of health insurance program beneficiaries.* An HMO may not request or encourage, by written or oral communication or by any action or inaction, a health insurance program beneficiary to disenroll, other than under the following circumstances:

(1) *Enrollee fails to pay premiums.* (i) An enrollee who is a health insurance program beneficiary and who fails to pay, pursuant to the HMO's written membership rules, the premiums or other charges imposed by the HMO for deductible and coinsurance amounts for which the enrollee is liable pursuant to § 417.222(b) may be disenrolled by the HMO provided that the HMO can demonstrate to the Secretary that it made reasonable efforts to collect the unpaid amount and gives written notice of termination of enrollment. Such notice shall be mailed to the enrollee prior to the submission of the disenrollment notice to the Social Security Administration. Such notice shall include an explanation of the enrollee's right to have any such disenrollment matter heard under the grievance procedures established pursuant to section 1301(c)(7) of the Public Health Service Act.

(ii) The liability of the Health Care Financing Administration to make monthly capitation payments to the HMO on behalf of such a beneficiary shall terminate as of the first day of the month in which the termination of his membership in the HMO as a health insurance program beneficiary is made effective, as shown on the records of the Social Security Administration. In no event will such month be earlier than the month immediately following, or later than the third month following, the month in which the disenrollment notice is received in acceptable form by the Social Security Administration.

(iii) Where the health insurance program beneficiary fails to pay the premium, or portion thereof, attributable to a supplemental benefit plan (but continues to pay other premiums), the beneficiary has contracted for, the HMO may cease to provide such supplemental coverage to such a beneficiary, as provided for in its membership rules, but may not disenroll the beneficiary for nonpayment of premiums applicable to a supplemental benefit plan.

(2) *Enrollee moves out of the HMO's service area or area in which enrollment of health insurance program beneficiaries is required.* A health insurance program beneficiary enrolled by the HMO as provided in § 417.220(b) may be disenrolled by the

HMO if he moves permanently out of the HMO's service area or area in which enrollment of health insurance program beneficiaries is required (see § 417.220(b)(2)) and does not voluntarily disenroll pursuant to paragraph (b) of this section. Where the HMO does not disenroll such a beneficiary, the HMO's enrollment area is not automatically expanded to include the geographic area of the beneficiary's new permanent residence, notwithstanding the provisions of § 417.205(a)(1). Where the HMO elects to disenroll a beneficiary who moves permanently outside the HMO's service area or area in which enrollment of health insurance program beneficiaries is required (see § 417.220(b)(2)) and such a beneficiary does not voluntarily disenroll, the HMO may do so provided that the HMO, on the basis of a written statement from the beneficiary or other evidence acceptable to the Social Security Administration, establishes that the beneficiary has permanently moved out of such an area and gives written notice of termination of enrollment to the beneficiary pursuant to the requirements of paragraph (a)(1)(i) of this section. In that event, the Health Care Financing Administration's liability to make monthly capitation payments to the HMO on behalf of the beneficiary shall terminate as of the first day of the month in which the termination of his membership in the HMO as a health insurance program beneficiary is made effective, as shown on the records of the Health Care Financing Administration. In no event will such month be earlier than the month immediately following, or later than the third month following, the month in which the disenrollment notice is received from the HMO in acceptable form by the Social Security Administration.

(3) *Enrollee dies.* The liability of the Health Care Financing Administration to make monthly per capita payment shall terminate effective with the month immediately following the month of death.

(4) *Enrollee's entitlement to benefits under the supplementary medical insurance program ends.* (i) The liability of the Health Care Financing Administration to make monthly capitation payments to the HMO on behalf of the beneficiary shall terminate effective with the month immediately following the last month of entitlement to benefits under the supplementary medical insurance program. The beneficiary may be continued as an enrollee other than a health insurance program beneficiary by the HMO under its regular plan if the HMO and the enrollee so choose.

(ii) Where an enrollee loses entitlement to benefits under the hospital insurance program, but remains entitled to benefits under the supplementary medical insurance program, he shall automatically continue as an enrollee of the HMO as a health insurance program beneficiary. He shall be entitled to receive and have payment made for services, as provided for in § 417.221 beginning with the month immediately following the last month of his entitlement to hospital insurance program benefits.

(5) *Enrollee commits fraud or permits abuse of HMO card.* A health insurance program beneficiary may be disenrolled by the HMO if such beneficiary knowingly provides, on the application form, fraudulent information upon which an HMO relies and which materially affects his or her eligibility to enroll in the HMO, or if the beneficiary intentionally permits others to use his or her membership card to receive services from the HMO. In either case, the HMO must give the beneficiary a written notice of termination of enrollment. Such notice must be mailed to the enrollee prior to the submission of the disenrollment notice to the Social Security Administration. Such notice shall include an explanation of the enrollee's right to have any such disenrollment heard under the grievance procedures established pursuant to § 417.257. The liability of the Health Care Financing Administration to make monthly capitation payments to the HMO on behalf of such a beneficiary shall terminate as of the first day of the month in which the termination of his membership in the HMO is made effective, as shown on the records of the Social Security Administration. In no event shall such month be earlier than the month immediately following, or later than the

third month following, the month in which the disenrollment notice is received in acceptable form by the Social Security Administration.

(b) *Beneficiary disenrollment.* A health insurance program beneficiary may disenroll from an HMO at any time by giving the HMO a signed, dated, written request on such form and in such manner as the HMO may require at least 30 days prior to the month in which he wishes the termination to be effective. In such cases, the HMO shall submit a disenrollment notice to the Social Security Administration within 30 days following the beneficiary's request. The liability of the Health Care Financing Administration to make monthly payments to the HMO on his behalf shall terminate with the close of the month of termination requested by the beneficiary, except that in no event shall the last month of payment be earlier than the month in which the beneficiary requested termination.

(c) *Disenrollment in cases of termination or default of contract.* (1) The termination of a contract between an HMO and the Secretary, whether by mutual consent or unilateral action by either party, shall result in the termination of the liability of the Health Care Financing Administration to make monthly capitation payments and the last month of liability shall be the last month for which the contract is effective.

(2) Where an HMO, for bankruptcy or other reasons, defaults in its contract with the Secretary prior to the close of the contract year, the Secretary shall establish the month in which the liability of the Health Care Financing Administration to make monthly capitation payments for all health insurance program beneficiaries enrolled in the HMO shall cease, and shall notify the HMO and such enrollees of his determination in writing as soon as practicable.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 5827, Feb. 10, 1978. Redesignated at 50 FR 1345, Jan. 10, 1985]

CONTRACT REQUIREMENTS

SOURCE: Sections 417.228 through 417.239, 44 FR 29061, May 18, 1979, unless otherwise noted. Redesignated at 50 FR 1345, Jan. 10, 1985.

§ 417.228 Basis, purpose, and scope.

Sections 417.229 through 417.239 implement those parts of section 1876 (a), (i), and (j) of the Social Security Act pertaining to the contract between the Secretary and an HMO under the Medicare program, and specify:

(a) Eligibility requirements and procedures for approval of a contract application;

(b) Basic contract requirements;

(c) Procedures for refunds; and

(d) Procedures for contract termination, renewals, and changes in ownership.

§ 417.229 Eligibility requirements and procedures for approval of a contract application.

An organization that wishes to contract as an HMO under the Medicare program on either a cost-basis or a risk-basis must submit an application and supporting information to HCFA in the form and detail required by HCFA. Whenever feasible, HCFA will not require an organization to resubmit information which it has already submitted to the Assistant Secretary for Health in connection with the determination required by paragraph (a)(1) of this section.

(a) *Eligibility requirements to enter into an HMO contract.* An organization will be determined eligible to enter into an HMO contract if:

(1) The Assistant Secretary for Health finds that it meets the qualifying conditions specified in §§ 417.201 through 417.207, or those conditions are waived as provided by these sections, and

(2) HCFA finds that:

(i) Entering into, or renewing, an HMO contract with the organization would be consistent with the effective and efficient administration of section 1876 of the Act. HCFA may not approve a contract under this paragraph if it finds that the organization:

(A) Lacks sufficient administrative capability to carry out the requirements of the contract;

(B) Has a conflict of interest that would interfere with the performance of its contract, or the administration of the Medicare program; or

(C) Has any persons with ownership or control interests, or agents or managing employees, who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare or the social services programs under title XX, and

(ii) In the case of an organization that is applying for a risk-basis contract, the organization:

(A) Has not previously voluntarily terminated or failed to renew a risk-basis contract under section 1876 of the Act; and

(B) Has the financial capability to assume the risk of any costs that might be reasonably anticipated during the contract period in excess of the adjusted average per capita cost for its area. Evidence of financial capability may include the purchase of an insurance program, or other financial arrangements that are satisfatory to HCFA.

(b) *Approval of application.* If HCFA determines that the organization meets the eligibility requirements specified in paragraph (a) of this section, HCFA will notify the organization in writing that:

(1) It is eligible to enter into a contract with the Secretary under 1876 of the Act—

(i) Either as a cost-basis HMO or as a risk-basis HMO or

(ii) Only as a cost-basis HMO;

(2) If the organization is dissatisfied with HCFA's determination that it is only eligible to enter into a contract as a cost-basis HMO, it may request a review of the determination by following the applicable procedures for reconsiderations of initial determinations specified in §§ 417.265 through 417.292; and

(3) If the organization wishes to be reimbursed as an HMO under Medicare, it must sign and submit a written contract that meets the requirements specified in §§ 417.230 through 417.236.

(c) *Denial of application.* If the organization does not meet the eligibility requirements specified in paragraph (a) of this section, HCFA will notify the organization in writing:

(1) That it is not eligible to enter into a contract with the Secretary under section 1876 of the Act;

(2) Of the reasons why the organization is ineligible for a contract; and

(3) That if it is dissatisfied with the notice of denial, it may request a review of the determination by following the applicable procedures for reconsiderations of initial determinations specified in §§ 417.265 through 417.292.

§ 417.230 General contract requirements.

(a) *Submittal of contract.* In order to be reimbursed as an HMO under Medicare, an eligible organization must sign and submit a written contract, in the form required by HCFA, that meets the requirements of this subpart and contains any other provisions required by HCFA.

(b) *General provisions of contract.* The contract must provide that the HMO agrees to comply with:

(1) Title VI of the Civil rights Act of 1964, as provided in § 417.265(c);

(2) Section 504 of the Rehabilitation Act of 1973, as amended;

(3) The requirements of Part B (Professional Standards Review) of title XI of the Social Security Act with respect to review of the services furnished its Medicare enrollees; and

(4) All provisions of this subpart.

(c) *Waived conditions.* All qualifying conditions that are waived (see § 417.229(a)(1)) must be specified in the contract. The specification must include:

(1) The specific terms of the waiver;

(2) The expiration date of the waiver; and

(3) Any other information that HCFA considers relevant.

(d) *Exemption from Federal Procurement Regulations.* Under the authority provided by section 1876(j) of the Act, the Federal Procurement Regulations and HHS Procurement Regulations contained in Title 41 CFR will not apply to contracts entered into under this subpart.

§ 417.231 Effective date and term of the contract.

(a) *Effective date.* The contract must specify its effective date, which may not be earlier than the date the contract is signed and executed by both the Secretary and the HMO.

(b) *Term.* The contract must specify its term.

(c) *Initial term.* The initial term of the contract may be not less than 12 months or more than 23 months.

(d) *Subsequent term.* Any subsequent term after the initial term will be for a period of 12 months.

(e) *Renewal.* A contract will be renewed automatically unless either party gives notice of its intent to terminate or not renew, as specified in § 417.238.

§ 417.232 Required services and organization.

The contract must specify that the HMO agrees to provide services, and is organized and operated, in the manner prescribed by section 1876(b)(1) (B) and (C) of the Social Security Act, and §§ 417.201 through 417.207 of this subpart.

§ 417.233 Charges, refunds, and recoupment.

(a) *Charges.* The contract must provide that the HMO agrees to charge its Medicare enrollees—

(1) For covered items and services only as provided in § 417.222(b).

(2) For noncovered items and services only as provided in § 417.222(a).

(b) *Refunds.* (1) The contract must provide that the HMO agrees to:

(i) Report all premiums, membership fees, and charges collected from its Medicare enrollees within 90 days after the close of the contract period; and

(ii) Refund all amounts incorrectly collected from its Medicare enrollees or from others on behalf of the enrollees, and any other amounts due Medicare enrollees or others on behalf of the enrollees.

(2) *"Money incorrectly collected".* This means sums collected in excess of the amount for which the enrollee was liable under § 417.222(b). It includes amounts collected at a time when the enrollee was believed not to be entitled to Medicare benefits but:

(i) The enrollee is later determined to have been entitled to Medicare benefits; and

(ii) The enrollees' entitlement period falls within the time the HMO's contract with the Secretary is in effect.

(3) *"Other amounts due".* This means amounts due an enrollee for items and services obtained from physicians, suppliers, or providers of services outside the HMO when:

(i) The enrollee is entitled to receive reasonable payment from the HMO for those items and services as provided in § 417.221(a)(2); and

(ii) The amount has been determined to be due the enrollee under the procedures specified in §§ 417.258 through 417.263.

(4) *Method of making refunds.* (i) An HMO must make refunds to its present and former Medicare enrollees by means of a lump sum payment in the following situations:

(A) For amounts incorrectly collected if the amounts were not collected on a premium basis;

(B) For other amounts due; and

(C) For all refunds if the HMO is going out of business.

If a former enrollee has died, or cannot be located after a reasonable effort on the part the HMO to do so, the HMO must make the refund in accordance with State law.

(ii) An HMO may use one of the following methods to refund money incorrectly collected on a premium basis (or through a combination of premiums and other charges) from one or more of its present or former Medicare enrollees:

(A) By a premium adjustment to the individual enrollee's or all enrollees' future years' premiums;

(B) By a lump sum payment to the enrollee; or

(C) By a combination of premium adjustment and lump sum payment.

(5) *Reduction by HCFA.* If the HMO does not comply with the requirements of paragraphs (b)(1)(ii) and (4) of this section by the close of the contract period following the one in which the amount was determined to be due, HCFA will reduce its payment to the HMO by the amount of the sums incorrectly collected or otherwise due, and will arrange for this amount to be paid to the HMO's Medicare enrollees.

(c) *Recoupment.* An HMO may collect from its Medicare enrollees, or from others on behalf of the enrollees, deductible and coinsurance charges for which they were liable (*see* § 417.222(b)) in a previous contract period if:

(1) The HMO's failure to collect these amounts during the contract period in which they were due resulted from:

(i) An underestimation of the actuarial value of the deductible and coinsurance amounts for the enrollees; or

(ii) A billing error or a miscalculation because of a mathematical error;

(2) The HMO identifies these amounts and obtains HCFA's advance approval to recoup these amounts and of the method and timing to be used for the recoupment. In the case of amounts specified in paragraph (c)(1)(i) of this section, the HMO collects these amounts through an adjustment to its enrollees' future premiums; and

(3) The HMO collects these amounts no later than 24 months following the end of the contract period in which they were due.

§ 417.234 Reinsurance.

The contract must provide that the HMO will be reimbursed for reinsurance only as specified in §§ 417.242(d) and 417.250(b).

§ 417.235 Coverage and enrollment.

(a) *Enrollment standards.* The contract must provide that the HMO agrees to have an enrollment that meets the standards specified in §§ 417.204(c), 417.220, and 417.223(b).

(b) *Enrollment period.* The contract must provide that the HMO agrees to have an open enrollment period that meets the requirements of § 417.223(a).

(c) *Continuity of services.* The contract must provide that the HMO agrees to continue providing care to its Medicare enrollees unless their enrollment is terminated according to § 417.225.

§ 417.236 Information access and disclosure requirements.

The contract must provide that the HMO agrees:

(a) That HHS or anyone designated by it may evaluate through inspection or other means the quality, appropriateness, and timeliness of services furnished under the contract to its Medicare enrollees;

(b) That HHS, the Comptroller General, or their designees may audit or inspect any books and records of the HMO or its transferee which pertain to services performed and determination of amounts payable under the contract.

(c) To maintain, as required by § 417.244, books, records, documents and other evidence of accounting procedures and practices.

(1) These records must be sufficient to:

(i) Assure an audit trail; and

(ii) Properly reflect all direct and indirect costs claimed to have been incurred under the contract.

(2) These records must include at least those pertaining to:

(i) Matters of ownership, organization, and operation of the HMO's financial, medical, and other recordkeeping systems;

(ii) Financial statements for the current contract period and three prior periods;

(iii) Federal income tax or information returns for the current contract period and three prior periods;

(iv) Asset acquisition, lease, sale, or other action;

(v) Agreements, contracts, and subcontracts;

(vi) Franchise, marketing, and management agreements;

(vii) Schedules of charges for the HMO's fee-for-service patients;

(viii) Matters pertaining to costs of operations;

(ix) Amounts of income received by source and payment;

(x) Cash flow statements; and

(xi) Any financial reports filed with other Federal programs or State authorities.

(d) To make available for the purposes specified in paragraphs (a) and (b) of this section, its premises, physical facilities and equipment, its records relating to its Medicare enrollees, the records specified in paragraph (c) of this section, and any additional relevant information that HCFA may require.

(e) That the right to inspect, evaluate, and audit, will extend through 3 years from the date of the final settlement for any contract period unless:

(1) HCFA determines there is a special need to retain a particular record or group of records for a longer period and notifies the HMO at least 30 days before the normal disposition date;

(2) HCFA finds that Federal or State laws require a longer retention period;

(3) There has been a termination, dispute, fraud, or similar fault by the HMO, in which case the retention period may be extended to 3 years from the date of any resulting final settlement; or

(4) HCFA determines that there is a reasonable possibility of fraud, in which case it may reopen a final settlement at any time.

(f) To require all subcontractors (as defined in § 420.201 of this chapter) that are related to the HMO by common ownership or control (see § 417.242(b)(11)), all entities that are related to the HMO by common ownership or control providing services to its Medicare enrollees, through either oral or written agreements, and all entities that are related to the HMO by common ownership or control with whom the HMO has leases of real property or total purchase orders in excess of $2,500 during the contract period to—

(1) Agree that HHS and the Comptroller General of the United States or their designees have the right to inspect, evaluate, and audit any pertinent books, documents, papers, and records of the subcontractor involving transactions related to the subcontract; and

(2) Agree that the right under paragraph (f)(1) of this section to information for any particular contract period will exist for a period equivalent to that specified in paragraph (e) of this section.

(g) To submit to HHS:

(1) All financial information as specified in §§ 417.247 and 417.254 for final settlement; and

(2) Any information or data that HHS determines is necessary for the administration or evaluation of the Medicare program.

(h) To comply with the disclosure requirements specified in Subpart C, Part 420 of this chapter.

(i) To comply with the requirements of the Privacy Act (5 U.S.C. 552(a)) and implementing regulations with respect to any system of records developed in performing its carrier or intermediary responsibilities. (See 45 CFR Part 5b.)

(j) To meet the confidentiality requirements specified in § 405.1026(a) of this chapter with respect to all medical and other information on enrollees not covered by paragraph (i) of this section that is contained in its records, or obtained from HHS or others.

§ 417.237 HMO Part A intermediary and Part B carrier responsibilities.

(a) *Part A intermediary responsibilities*—(1) *Election required.* The contract must provide that the HMO will elect, according to § 417.241(d):

(i) To have HCFA pay providers of services for covered items and services furnished to its Medicare enrollees;

(ii) To assume responsibility for paying providers of services directly for covered items and services furnished its Medicare enrollees; or

(iii) To use a combination of the methods specified in paragraphs (a)(1)(i) and (ii) of this section, if approved by HCFA.

(2) *Direct reimbursement by HMO.* If the HMO elects to pay providers of services directly for covered items and services, the HMO must:

(i) Determine the eligibility of its Medicare enrollees to receive covered items and services through the HMO;

(ii) Make proper coverage decisions and appropriate payments, in accordance with this part, for covered items and services for which its Medicare enrollees are eligible;

(iii) Assure that providers of services maintain and furnish appropriate documentation of physician certification and recertification, to the extent required by Subpart B of Part 424 of this chapter; and

(iv) Carry out any other procedures which HCFA may from time to time require.

(3) *Review of HMO bill processing capabilities.* If the HMO elects to pay providers of services directly, HCFA will determine whether the HMO has the experience and capability to carry out efficiently and effectively the responsibilities specified in paragraph (a)(2) of this section.

(4) *HCFA direct reimbursement required.* If HCFA determines that the HMO is not carrying out its bill-processing operations properly (or does not have the experience or capability to do so in the future), it may require the HMO to elect to have HCFA pay its providers of services directly. If the HMO refuses this election, HCFA may decline to enter into or may terminate a contract with the HMO.

(b) *Part B carrier responsibilities.* The contract must provide that in making reimbursement for non-provider Part B services furnished to its enrollees, an HMO is responsible for:

(1) Determining the eligibility of individuals to receive such items and services through the HMO;

(2) Making proper coverage decisions and appropriate payment, in accordance with the requirements of this part, for items and services for which its Medicare enrollees are eligible; and

(3) Carrying out any other procedures which HCFA may from time to time require.

[44 FR 29061, May 18, 1979. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 53 FR 6648, Mar. 2, 1988]

§ 417.238 Non-renewal, termination, or modification of a contract.

(a) *Non-renewal by HMO.* (1) If an HMO does not intend to renew its contract, it must:

(i) Give written notice to HCFA at least 90 days before the end of the current contract period;

(ii) Notify each Medicare enrollee by mail, at least 60 days before the end of the contract period; and

(iii) Notify the general public at least 30 days before the end of the contract period, by publishing a notice in one or more newspapers of general circulation in each community or county located in the HMO's enrollment area.

(2) The Secretary, at his discretion, may accept a non-renewal notice submitted less than 90 days before the end of the contract period if:

(i) The HMO notifies its Medicare enrollees and the public in accordance with paragraphs (a)(1)(ii) and (iii) of this section; and

(ii) Acceptance would not otherwise jeopardize the effective and efficient administraion of the Medicare program.

(b) *Termination or modification by mutual consent.* An HMO and the Secretary may modify or terminate the contract at any time by written mutual consent.

(1) *Modification.* If the contract is modified, the HMO must notify its Medicare enrollees of any modifications which the Secretary determines is appropriate.

(2) *Termination.* If the contract is terminated:

(i) The HMO must notify its Medicare enrollees at least 30 days before the termination date; and

(ii) HCFA will notify the public at least 30 days before the termination date.

(c) *Non-renewal by the Secretary.* The Secretary may decide not to renew the HMO's contract at the end of the term. If the Secretary decides not to renew a contract, he will:

(1) Notify the HMO at least 90 days before the end of the contract period;

(2) Notify the HMO's Medicare enrollees at least 60 days before the end of the contract period;

(3) Notify the general public at least 30 days before the end of the contract period; and

(4) Notify the HMO that if it is dissatisfied with the decision, it may request a review of the decision by following the procedures for reconsiderations of initial determinations specified in §§ 417.265 through 417.292.

(d) *Termination by the Secretary.* The Secretary may terminate a contract during its term for any of the reasons specified in § 417.266(b)(1)-(3) by:

(1) Following the procedures specified in §§ 417.265 through 417.292; and

(2) Notifying the HMO's enrollees and the general public at least 30 days before the effective date of the termination.

§ 417.239 Transfer of HMO ownership.

(a) *General rule.* (1) A transfer of the ownership or operation of an HMO, as specified in paragraphs (b), (c), (d), and (e) of this section, will render the contract invalid between the Secretary and the transferee, unless HCFA has approved a third party as the successor in interest to the contract through a novation agreement, as provided in paragraphs (f) and (g) of this section.

(2) An HMO which is contemplating or negotiating a change of ownership must notify HCFA at least 60 days in advance of the anticipated change of ownership. If it does not, the HMO (transferor) will continue to be liable to HCFA for per capita payments made to it by HCFA on behalf of its Medicare enrollees after the effective date of the transfer of ownership.

(3) If a change of ownership takes place without a novation agreement, the contract becomes invalid. If the new owner wishes to participate as an HMO under Medicare, it must:

(i) Notify HCFA that there has been a transfer of ownership of the HMO without a novation agreement; and

(ii) Apply for and enter into a contract as an HMO under Medicare, as specified in §§ 417.229 through 417.236.

(b) *Partnership.* In the case of a partnership, a change of ownership takes place in the circumstances specified in § 489.18(a)(1) of this chapter.

(c) *Sole proprietorship.* In the case of a sole proprietorship, a change of ownership takes place in the circumstances specified in § 489.18(a)(2) of this chapter.

(d) *Corporation.* (1) If an HMO is a corporate body, a change of ownership does not ordinarily occur if:

(i) There is a transfer of corporate stock; or

(ii) There is a merger of one or more corporations, with the HMO corporation surviving.

(2) A merger of two or more corporations involving an HMO corporation does constitute a change of ownership if the merger results in a new corporate entity.

(e) *Leasing.* If an HMO leases its facilities, in whole or in part, to another entity, the lessee does not assume HMO status under section 1876 of the Act.

(1) If the HMO leases all of its facilities to another organization, the Secretary's contract with the lessor organization terminates unless he has approved the transaction in advance.

(2) If the HMO leases part of its facilities to another organization, the contract remains in effect. However, HCFA will conduct a survey to determine whether the HMO continues to be in compliance with the HMO qualifying conditions specified in §§ 417.201 through 417.207.

(3) If the lessee of the facilities wishes to participate as an HMO under the Medicare program, it must apply for and enter into a contract with the Secretary as specified in §§ 417.229 through 417.236.

(f) *Provisions of novation agreement*—(1) *Definition.* "Novation agreement" means the legal instrument executed by the current owner (transferor of an HMO), the proposed new owner (transferee) of an HMO, and HCFA, under which HCFA recognizes the transferee as the successor in interest to the existing contract.

(2) *Provisions.* (i) The transferee must assume all obligations under the contract; and

(ii) The transferor must waive its rights under the contract to obtain from the Secretary reimbursement for covered services furnished during the current contract period.

(3) *Guarantee of performance.* The transferor must guarantee performance of the contract by the transferee, or the transferee must post a satisfactory performance bond which is approved by HCFA.

(4) *Records access.* The transferor must agree to make its books, records, and other necessary information available to the transferee and to HCFA to permit an accurate determination of costs for the final settlement of the contract period.

(g) *Requirements for HCFA approval of a novation agreement.* A novation agreement may be approved and executed by HCFA if:

(1) The HMO (transferor) notifies HCFA at least 60 days in advance of the proposed change of ownership;

(2) The HMO submits, at least 30 days before the anticipated date of change of ownership, three signed copies of a proposed novation agreement to HCFA and one copy of any other documents required by HCFA; and

(3) HCFA determines that:

(i) The proposed transferee is in fact a successor in interest to the contract;

(ii) Recognition of the new party as a successor in interest to the contract with the HMO is in the best interest of the Medicare HMO program; and

(iii) The successor organization meets the requirements of this subpart to qualify as an HMO.

PRINCIPLES OF REIMBURSEMENT FOR COST-BASIS HMO'S UNDER TITLE XVIII

SOURCE: Sections 417.240 through 417.247 appear at 41 FR 49595, Nov. 9, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977, and at 50 FR 1345, Jan. 10, 1985.

§ 417.240 Reimbursement of cost-basis HMO's—introduction.

(a) A developing HMO, or a mature HMO that elects to be reimbursed on a cost basis (see § 417.201(b) for definitions of mature and developing HMO's), is paid the "reasonable cost" of the covered services it furnishes to its enrollees who are beneficiaries under title XVIII of the Act. The principles of reimbursement and guidelines to be used in determining the reasonable costs of such HMO's are set forth in §§ 417.241 through 417.247. Since the law contemplates that only those costs which are allowable under title XVIII of the Act generally may be recognized as allowable HMO costs, the principles and related policies in §§ 417.241 through 417.244 are based, in large part, on the principles of reimbursement for provider costs (see Parts 412 and 413 of this chapter).

(b) The principles governing cost reimbursement to HMO's offer certain alternatives and options to HMO's in order to reflect the variation in operations among HMO's. For example, in § 417.243(h) the principles applicable to developing HMO's allow time for those that do not already have the capability of reporting statistical and financial data by departments or functional service centers to meet this requirement. The principles governing cost reimbursement to HMO's also take into account the special nature of the HMO by recognizing costs of marketing, enrollment, and certain other costs that are unique to the HMO form of health care delivery.

[41 FR 49595, Nov. 9, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 34832, Sept. 30, 1986]

§ 417.241 Cost reimbursement—general.

(a) The costs incurred by the HMO in providing services covered under the hospital insurance program and supplementary medical insurance program are reimbursable if proper and necessary, reasonable in amount, and appropriately apportioned among enrollees who are title XVIII beneficiaries, other enrollees, and nonenrolled patients of the HMO. Implicit in the intention that the amount paid be reasonable is the expectation that each HMO will seek to minimize the costs that it incurs in furnishing this care so that its actual costs will not exceed what a prudent and cost-conscious buyer would incur in furnishing such care.

(b) In formulating methods for making fair and equitable reimbursements to HMO's for services rendered to title XVIII beneficiaries who are enrolled in such organizations, the cost reimbursement principles set forth in paragraphs (a) and (b) of § 413.5 of this chapter shall apply. In evaluating the reasonableness of costs, for a cost-basis HMO, the Health Care Financing Administration (hereafter referred to as HCFA) shall also take into account the HMO's per capita incurred costs for providing covered services to enrollees who are title XVIII beneficiaries in relation to the adjusted average per capita cost as described in section 1876(a)(3)(A)(iv) of the Act for the geographic area served by the HMO, or a similar area. In such cases, the adjusted average per capita cost shall be used as a general guideline to evaluate the reasonableness of HMO costs rather than a strict reimbursement limitation as is the case with risk-basis HMO's (see § 417.251).

(c) HCFA shall determine an interim per capita cost rate of payment in accordance with § 417.245 which shall be paid to the HMO each month, in advance, for each title XVIII beneficiary enrolled with the HMO for which the health insurance program is responsible for making such a payment pursuant to this subpart. HCFA shall adjust the interim per capita rate to the extent necessary, as provided in § 417.245(c). Interim payments shall be subject to retroactive adjustment at the end of each contract period as provided in §§ 417.246 and 417.247. In determining the amount due the HMO, there shall be deducted from the reasonable cost actually incurred by the HMO, for covered services furnished title XVIII beneficiaries enrolled with the HMO, an amount equal to the actuarial value of the deductible and coinsurance amounts which would otherwise be applicable to the covered services for which payment is being made if the title XVIII beneficiaries who received the services had not been enrolled in the HMO.

(d) An HMO may elect to have providers of services that furnish covered services to enrollees who are title XVIII beneficiaries, obtain reimbursement directly from the health insurance program. The election, which is binding for the entire contract period, must be made in writing to HCFA prior to the beginning of the contract period. When the HMO makes the election, the providers are each paid for covered services they furnish enrollees of the organization in accordance with Parts 412 and 413 of this chapter. The amount of such reimbursement will not be included in payments made to the HMO.

[41 FR 49595, Nov. 9, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 39837, Sept. 1, 1983. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 34832, Sept. 30, 1986]

§ 417.242 Allowable costs.

(a) *General.* Allowable costs are those direct and indirect costs, including normal standby costs, which are incurred by the HMO and are proper and necessary to the efficient delivery by the HMO of needed health care. Such costs include those related to the care of beneficiaries under title XVIII, enrollment, membership, and similar costs that are proper and necessary to the HMO plan operations. The treatment of certain items of costs following, in essence, the principles of reimbursement for provider costs is discussed in paragraph (b) of this section. The treatment of other items of cost is described in paragraphs (c) through (i) of this section.

(b) *Provider cost reimbursement principles applicable to HMO's.* The types and items of cost generally incurred by providers of services that are allowable under the principles of reimbursement for provider costs (see Parts 412 and 413 of this chapter), including the following items, are allowable when incurred by an HMO or by providers of services and other facilities owned or operated by the HMO through which covered care is furnished to the HMO's enrollees who are title XVIII beneficiaries, unless otherwise specified in this subpart:

(1) *Depreciation.* An appropriate allowance for depreciation on buildings and equipment is an allowable expense. The HMO shall follow the provisions of §§ 413.134, 413.144, and 413.149 of this chapter.

(2) *Interest expense.* Necessary and proper interest on both current and capital indebtedness is an allowable expense in accordance with § 413.153 of this chapter.

(3) *Bad debts.* Bad debts are deductions from revenue and are not to be included in allowable costs; however, bad debts attributable to deductible and co-insurance amounts for Part A and Part B covered services for which the beneficiary is liable in a contract period pursuant to § 417.222(b) are reimbursable under the health insurance program in accordance with the provisions of § 413.80 of this chapter.

(i) When deductible and coinsurance amounts are paid by all or a portion of a monthly premium, or other periodic amount, the amount of allowable bad debts for an enrollee who is a title XVIII beneficiary for a contract period shall be limited to an amount not to exceed three times the monthly rate for the actuarial value of the deductible and coinsurance amounts, or its equivalent if the periodic charge or premium is payable on other than a monthly basis.

(ii) Any bad debt related to a service furnished to an enrollee of the HMO who is a title XVIII beneficiary and claimed on a cost report submitted for reimbursement under title XVIII of the Act by a provider of services, or other facility reimbursed on a cost basis, may not be claimed as a bad debt by the HMO.

(4) *Charity and courtesy allowances.* Charity and courtesy allowances are deductions from revenue and are not to be included in allowable costs in accordance with § 413.80 of this chapter.

(5) *Cost of educational activities.* An appropriate part of the net cost of approved educational activities engaged in by a provider of services or other health care facility owned or operated by the HMO is an allowable cost in accordance with § 413.85 of this chapter.

(6) *Research costs.* Cost incurred for research purposes, over and above usual patient care, in accordance with § 413.90 of this chapter, are not includable in allowable costs of the HMO.

(7) *Grants, gifts, and income from endowments.* Grants, gifts, and income from endowments are treated in accordance with § 405.423[1].

(8) *Value of services of nonpaid workers.* The value of services of certain nonpaid workers is an allowable cost in accordance with § 413.94 of this chapter.

(9) *Purchase discounts and allowances and refunds of expenses.* Discounts and allowances received on purchases of goods and services are reductions of the HMO's costs to which they relate. Similarly, refunds of previous expense payments are reductions of the related expense in accordance with § 413.98 of this chapter.

(10) *Compensation of owners.* A reasonable allowance of compensation for services of owners is an allowable cost provided that the services are actually performed in a necessary function in accordance with § 413.102 of this chapter.

(11) *Cost to related organizations.* Costs applicable to services, facilities, and supplies furnished to the HMO by organizations related to the HMO by common ownership or control are includable in the allowable cost of the HMO at the cost to the related organization. However, such cost must not exceed the price of comparable services, facilities, or supplies which would be paid by a prudent buyer purchasing elsewhere. The provisions of § 413.17 of this chapter are applicable to HMO's; however, in applying those provisions to HMO's, a provider of services, medical group, or other facility or supplier is not deemed a related organization solely because of a risk-sharing or incentive agreement with an HMO for reimbursement or compensation for services furnished HMO enrollees, or solely because substantially all services furnished by the provider or supplier are furnished enrollees of the HMO. However, such an economically dependent organization and the HMO shall be considered related if one of them clearly exercises significant management or ownership influence or control over the other.

(12) *Return on equity capital of proprietary providers owned by the HMO.* An allowance for a reasonable return on equity capital invested and used in the provision of patient care is allowable as an element of the reasonable cost of covered services furnished by a proprietary provider of services owned by an HMO in accordance with § 413.157 of this chapter.

(13) *Limitation on Federal participation for capital expenditures.* Section 1122 of the Social Security Act prohibits the use of Federal funds to support certain capital expenditures made by or on behalf of HMO's (or health care facilities) that are determined to be inconsistent with State or local health facility planning requirements. HMO's are subject to the provisions of section 1122 in accordance with the principles in §§ 413.5, 413.134, 413.153, 413.157, and 413.161 of this chapter.

(14) *Title XVIII limitations on reimbursement.* (i) Unless otherwise specified in this subpart, the reimburse-

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[1] Section 405.423 was removed at 48 FR 39811, Sept. 1, 1983.

ment limitations imposed on the amounts payable to providers of services and other health care facilities under section 1861(v) of the Social Security Act apply to the amount payable by the health insurance program for covered services furnished by providers of services or other health care facilities that are owned or operated by a cost-basis HMO or are related to the cost-basis HMO by common ownership or control, and for services furnished by providers of services or other health care facilities that are reimbursed on a reasonable-cost basis. The reimbursement limitations applicable to cost-basis HMO's include, but are not necessarily limited to, the following:

(*a*) The cost of treatment for chronic renal disease (§ 405.502(e) and § 413.5(f) of this chapter);

(*b*) The limitation on coverage of costs set forth in § 413.30 of this chapter;

(*c*) The reasonable cost of physical and other therapy services furnished under arrangements (§ 413.106 of this chapter);

(*d*) The allowable cost for drugs under § 413.110 of this chapter.

(ii) The limitation on health insurance program payment to the lesser of the reasonable cost or customary charges for covered services (§ 413.13 of this chapter) does not apply with respect to services furnished to an HMO's enrollees who are title XVIII beneficiaries by a provider of services or other health care facility owned or operated by the HMO or related to the HMO by common ownership or control.

(c) *Enrollment and marketing costs*—(1) *Principle.* Enrollment and marketing costs incurred in accordance with § 417.223 are allowable costs. (See § 417.243(f) and § 417.244.)

(2) *Definition.* Allowable enrollment and marketing costs are those necessary and proper costs incurred in offering the HMO's plan to potential enrollees in accordance with this subpart. Such costs include selling, advertising, promotional, and other marketing costs and may not exceed an amount that would be incurred by a prudent and cost-conscious management.

(3) *Application.* Membership costs, described in paragraph (e) of this section, are not included in enrollment and marketing costs. Enrollment and marketing costs are allowable, whether incurred directly by HMO staff or under contract with marketing specialists or other outside consultants.

(4) *Enrollment and marketing costs reimbursement limitation.* The relatively higher costs that a developing HMO is likely to incur in offering its plan to title XVIII beneficiaries and that a mature HMO is likely to incur in initially offering its plan to title XVIII beneficiaries are taken into account in determining whether enrollment and marketing costs are reasonable in amount. However, if such costs exceed amounts which would be paid by prudent HMO management, the excess shall not be allowed.

(d) *Reinsurance.* (1) The health insurance program's share of reasonable costs for reinsurance (i.e., protection against all or part of the financial risk that the HMO is obligated to assume under its subscriber agreement with enrollees who are title XVIII beneficiaries) is allowable to the extent that the HMO incurs reinsurance costs for:

(i) Covered emergency services (§ 417.205(a)(3)(i)) furnished outside the HMO's service area (§ 417.205(a)(1)),

(ii) Covered urgently needed services (§ 417.205(a)(3)(ii)) furnished outside the HMO's enrollment area (§ 417.205(a)(1)), and

(iii) Other covered items and services furnished outside the HMO's enrollment area through arrangements (§ 417.205(a)(2)).

(2) If the actual cost of reinsurance cannot be readily determined for the covered items or services, which are specified in paragraph (d)(1) of this section and are furnished to enrollees who are title XVIII beneficiaries, a reasonable estimate may be used.

(3) When the HMO's reinsurance covers only part of the cost of such covered services described in paragraph (d)(1) of this section, the share to be borne by the health insurance program for the cost of these covered services, including reinsurance cost and other payments, shall not exceed the amount that would otherwise be

paid under this subpart. Other reinsurance costs are not allowable.

(e) *Membership costs*—(1) *Principle.* Membership costs are allowable (see §§ 417.243(f) and 417.244(e) on cost apportionment and cost finding).

(2) *Definition.* Membership costs are allowable if incurred in maintaining and servicing subscriber contracts for prepayment enrollees. Membership costs include, but are not limited to: reasonable costs incurred in connection with maintaining statistical, financial, and other data on members.

(3) *Application.* For health insurance program purposes, membership costs shall not be included with allowable enrollment and marketing costs or with costs described in paragraph (i) of this section.

(f) *Physician compensation*—(1) *Principle.* Compensation paid by an HMO to physicians is an allowable cost to the extent that such compensation is commensurate with the compensation paid for similar services performed by similar physicians practicing in the same or similar locality. To the extent such compensation cost is in excess of what is normally incurred, the excess is not an allowable cost.

(2) *Application.* Compensation for the personal services of physicians (i.e., salaries, wages, incentive payments, fringe benefits, etc.) shall be distinguished from payments to physicians for nonpersonal services (i.e., expense attributable to facilities, equipment, support personnel, supplies, etc.) in determining whether compensation is allowable. Physicians influence the management of an HMO to a very significant degree, and, therefore, directly affect the costs of services and the financial status of an HMO. Their compensation may take various forms, but it is intended that the aggregate compensation allowable be reasonable in relation to the services personally rendered. Reasonableness of compensation may be determined by reference to, or in comparison with, compensation paid for comparable services and responsibilities.

(g) *Physicians' services under arrangements.* (1) The amount paid by an HMO to a physician group (organized on a group-practice or individual-practice basis) for physicians' services, and for other covered Part B services, furnished under arrangements (as described in § 110.104 of this title), is an allowable expense to the extent it is reasonable.

(2) The amount paid by an HMO on a-fee-for-service basis to physicians and other suppliers and to a physician group organized on an individual-practice basis for physicians' services and other covered Part B services furnished under arrangements (as described in § 110.104 of this title) is an allowable expense to the extent it is not in excess of the reasonable charges, as defined in Subpart E of Part 405 of this chapter. Therefore, payment is limited to the amount that would otherwise be paid if the services were furnished by the physician group (or by similar physicians, practitioners, or suppliers) to Medicare beneficiaries who are not enrolled in the HMO. The same limitation also applies to the amount paid by the HMO for such covered services furnished under arrangements with a physician, physician-directed clinic, or a supplier of services.

(3) However, an exception to the reasonable charges limitation described in paragraph (g)(2) of this section is permitted, if the HMO demonstrates to HCFA's satisfaction that the physician group organized on an individual-practice basis has an agreement that includes acceptance by the members of the physician group of effective incentives, such as risk-sharing or other financial incentives, designed to avoid unnecessary or unduly costly utilization of health services. In such cases, the amount of physician compensation paid by an HMO is an allowable expense to the extent it is reasonable.

(h) *Provider services through arrangements.* The cost incurred by an HMO for covered services furnished by a provider through arrangements (see § 110.104 of this title and § 417.243(b)) are allowable to the extent that such cost would be allowable and reimbursable pursuant to Subpart D of Part 405 of this chapter unless the HMO can demonstrate to the satisfaction of HCFA that payment in excess of the reasonable cost allowed pursuant to such Subpart D of Part 405 of this chapter is justified on the basis of advantages gained by the HMO. For example, if an HMO has an arrangement with a provider of services located outside the HMO's enrollment area that is not related to the HMO by common ownership or control, payment for the provider's charges to the HMO for covered services (rather than the provider's reasonable cost as determined under Parts 412 and 413 of this chapter) may be justified if: The provider furnishes services to enrollees of the HMO on an infrequent basis; the charges represent an insignificant amount of total reimbursement to the HMO by the program; and the charges do not exceed the customary charges by the provider to its other patients for similar services. The advantages gained under this arrangement include a more timely final settlement with the HMO and the elimination of administrative costs necessary to determine the provider's reasonable cost for these services. An advantage gained represents a real and tangible benefit received by the HMO for the excess cost incurred. Any such excess payment is also subject to other applicable requirements of Part 405 of this chapter, including tests of reasonableness.

(i) *Special Title XVIII program requirements.* (1) The total reasonable cost incurred by an HMO for services specified in this paragraph, which are solely for the purposes of the health insurance program and unique to the health insurance program's HMO provision, shall be reimbursed in full by the program. However, in reimbursing for the cost specified in this paragraph for an independently certified cost report, only those additional costs incurred by an HMO that are related to the certification of the HMO's cost report are reimbursable in full by the program. The normal administrative costs incurred by the HMO in obtaining reimbursement from the health insurance program (such as the cost of maintaining and reporting statistical and acturial data needed to determined the amount of reimbursement due the HMO and the cost of preparing cost reports) are apportioned to the health insurance program (see § 417.243(f)). The reasonable cost of preparing independently certified financial statements for the HMO and the reasonable cost of other HMO management services are also apportioned in accordance with § 417.243(f). Costs that are reimbursable in full under this paragraph shall be separately budgeted and approved in advance of the contract period. The following costs shall be reimbursed in full as specified in this paragraph.

(i) The reasonable cost of reporting individual title XVIII beneficiary enrollment accretion and deletion data; and

(ii) The reasonable cost incurred solely for the purposes of title XVIII for the HMO's independently certified cost report described in § 417.247(b) for cost-basis HMO's and in § 417.254(b) for risk-basis HMO's.

(2) The total reasonable cost of special data required from HMO's by the health insurance program solely for program evaluation and planning purposes shall be reimbursed in full by the program under the requirements of paragraph (i)(1) of this section. Except as specifically provided for, paragraph (i)(1) of this section shall not apply to data the HMO is required to maintain and furnish HCFA under any other provision of this subpart.

[41 FR 49596, Nov. 9, 1976; 41 FR 53320, Dec. 6, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 47 FR 58258, Dec. 30, 1982. Redesignated and amended at 50 FR 1345, Jan. 10, 1985; 51 FR 34832, Sept. 30, 1986]

§ 417.243 Cost apportionment.

(a) *General.* Total allowable direct and indirect costs of an HMO shall be apportioned among title XVIII beneficiaries who are enrolled in the HMO, other enrollees, and any nonenrolled patients of the HMO. This apportionment shall be accomplished on the basis of requirements set forth in this section using methodologies approved by HCFA. (See § 417.242(i) for reimbursement of costs incurred in meeting special title XVIII program requirements.) The two basic objectives of this apportionment are that, to the extent reasonably possible, (1) the costs of efficiently delivering covered care to enrollees who are title XVIII beneficiaries will not be borne by other enrollees, and by any nonenrolled patients of the HMO, and (2) the costs of delivering care to enrollees other than enrollees who are title XVIII beneficiaries and any nonenrolled patients will not be borne by the health insurance program under section 1876 of the Act. (The HMO shall be reimbursed for covered services furnished to title XVIII beneficiaries not enrolled in the HMO through the HMO's health insurance program fiscal intermediary or carrier, as appropriate.)

(b) *Methods of apportionment for provider services*—(1) *Provider services furnished directly by the HMO.* The method of apportionment required by §§ 405.480, 413.55, and 413.24 of this chapter shall be used to determine the share to be borne by the health insurance program for the cost of covered services furnished to enrollees who are title XVIII beneficiaries directly by the HMO through a "provider of services" (as defined in § 413.1 of this chapter) which is owned or operated by the HMO, or related to the HMO by common ownership or control (see § 417.244(c) for cost-finding requirements).

(2) *Provider services furnished by the HMO through arrangements with others.* The share to be borne by the health insurance program for covered services furnished to enrollees who are title XVIII beneficiaries, by the HMO through arrangements with a provider of services which is not owned or operated by the HMO, or related to the HMO by common ownership or control, shall be determined as follows:

(i) The share to be borne by the health insurance program for covered services furnished to enrollees who are title XVIII beneficiaries by the provider shall be based on the cost the HMO pays the provider, pursuant to its financial arrangement with the provider, to the extent it is reasonable and subject to conditions and limitations set forth in § 417.242(a). The share to be borne by the health insurance program shall be determined on the same approved basis otherwise used by the provider in apportioning the health insurance program's share of allowable costs for covered services furnished title XVIII beneficiaries that are not enrollees of the HMO subject to conditions and limitations set forth in § 417.242(h). In the event that apportionment on this basis, because of the special nature or terms of the HMO's financial arrangement with the provider, would result in the health insurance program's bearing the costs of delivering care to individuals other than enrollees who are title XVIII beneficiaries, the apportionment shall be on some other appropriate basis approved by HCFA, intended to assure that the share allocated to the health insurance program does not include costs of delivering care to individuals other than enrollees who are title XVIII beneficiaries.

(ii) Where the HMO elects to have providers of services seek reimbursement from their health insurance program intermediary for covered services furnished to the HMO's enrollees who are title XVIII beneficiaries, the share to be borne by the health insurance program for covered services shall be the amount paid the provider pursuant to § 417.241(d).

(3) *Emergency services; urgently needed services and out-of-area provider services for which the HMO assumes financial responsibility.* Providers of services may be reimbursed through their health insurance program intermediary for the reasonable cost of covered emergency services (as defined in § 417.205(a)(3)(i)), urgently needed services (as defined in § 417.205(a)(3)(ii)), and other covered out-of-area services for which the HMO assumes financial responsibility, except for services covered under reinsurance, the cost of which is allowable pursuant to § 417.242(d), in accordance with Parts 412 and 413 of this chapter. The amount of such reimbursement will not be included in payments made to the HMO. If an HMO pays the provider of services for emergency, urgently needed, and other covered out-of-area services, the cost incurred by the HMO shall be allowable and reimbursable under Parts 412 and 413 of this chapter, unless the HMO can demonstrate to the satisfaction of HCFA that payment in excess of the reasonable cost allowed under Parts 412 and 413 of this chapter is justified on the basis of advantages gained by the HMO as described in § 417.242(h).

(c) *Methods of apportionment of covered physicians' services and other covered Part B services which are not provider services*—(1) *Medical services furnished directly by the HMO.* The total allowable direct and indirect costs of covered physicians' services and other Part B services not furnished through a provider of services, but which the HMO furnishes directly through physicians and other health care personnel who are employees or partners of the HMO, or by a group of physicians or by a health center or other facility which is related to the HMO by common control or ownership, shall be apportioned on the basis of the ratio of covered Part B services provided to enrollees who are title XVIII beneficiaries to total services furnished to all enrollees of the HMO and other patients on a departmental basis. The sum of the apportioned costs for each department furnishing covered services is the total share of the medical costs to be borne by the health insurance program (see example in paragraph (e) of this section for services furnished directly).

(2) *Medical services furnished under arrangements by the HMO.* The share to be borne by the health insurance program of the cost of covered physicians' services and other Part B services not furnished through a provider of services, but which the HMO furnishes to its enrollees who are title XVIII beneficiaries under arrangements such as with a group of physicians (organized on a group-practice or individual-practice basis) shall be determined as follows:

(i) The share to be borne by the health insurance program for covered Part B services furnished to the HMO's enrollees who are title XVIII beneficiaries under an arrangement whereby the HMO pays for the services on some basis other than fee-for-service shall be based on the cost the HMO pays, pursuant to its financial arrangement with the group of physicians or supplier, to the extent it is reasonable. The share to be borne by the health insurance program under this arrangement shall be determined on the basis of a ratio of the covered services furnished to the HMO's enrollees who are title XVIII beneficiaries to total services furnished to the HMO's enrollees and other patients covered by the payment, except where apportionment on this basis would result in the health insurance program's bearing the costs of delivering care to individuals who are not title XVIII beneficiaries. In that event, apportionment shall be on some other appropriate basis approved by HCFA so that the share allocated to the health insurance program does not include costs of delivering care to individuals who are not title XVIII beneficiaries.

(ii) The share to be borne by the health insurance program for covered Part B services furnished by the HMO to its enrollees who are title XVIII beneficiaries under an arrangement whereby the HMO pays for the services on a fee-for-service basis shall be the charges pursuant to the terms of the agreement for these covered services provided these charges do not exceed the reasonable charge for the service, as defined in Subpart E of Part 405 of this chapter. However, an exception to this reasonable charges limitation is permitted a physician group organized on an individual-practice basis that meets the conditions set forth in § 417.242(g)(3).

(3) *Emergency services, urgently needed services and other covered medical services for which the HMO assumes financial responsibility.* The share to be borne by the health insurance program for covered physicians' services and other covered Part B services which are not furnished by a provider of services and are emergency services (as defined in § 417.205(a)(3)(i), urgently needed services (as defined in § 417.205(a)(3)(ii)), or other covered services for which the HMO assumes financial responsibility, except for services covered under reinsurance, the cost of which is allowable pursuant to § 417.242(d), shall be determined in accordance with paragraph (c)(2) of this section, unless payment of a greater amount is justified to the satisfaction of HCFA. For example, payment of the charges of a physician or other Part B supplier rather than reasonable charge for the service as defined in Subpart E of Part 405 of this chapter may be justified if:

The physician or other Part B supplier furnishes services to enrollees of the HMO on an infrequent basis; such charges represent an insignificant amount of total reimbursement to the HMO by the program; and such charges do not exceed the amounts charged by such physician or other Part B supplier to other patients for similar services.

(d) *Weighting for services of physicians and other health care personnel.* (1) Since the direct professional services of physicians and other health care personnel vary in time and complexity from patient to patient, depending on the patient's condition and other factors, the HMO may weight for time and complexity the services that are used to compute the apportionment of costs for the direct professional services of physicians and other health care personnel pursuant to paragraph (c)(1) of this section provided such weighting is approved by HCFA. The HMO may use statistics or reasonable estimates that are based on adequate data acceptable to HCFA. However, services used in apportionment ratios for each department, i.e., services furnished title XVIII beneficiaries who are enrolled in the HMO, other enrollees, and nonmember patients, must be weighted on the same basis to assure an equitable apportionment of costs.

(2) Such weighting shall be permitted, subject to the payment limitation set forth in § 417.242(g), if applicable, in making reimbursement for the covered Part B professional services of physicians and other health care personnel furnished under arrangements where apportionment is on the basis of services, pursuant to paragraph (c)(2)(i) of this section, provided such weighting is based on statistics or adequate data acceptable to HCFA and all services used in the apportionment ratio are weighted on the same basis. Where payment for such arranged-for services is on some other basis, time and complexity shall be recognized subject to the payment limitation in § 417.242(g), if applicable, but only to the extent that they are specific and reasonable elements of the amount which the HMO, pursuant to the terms of the financial agreement with the group of physicians, has agreed to pay for such services.

(e) *Example.* The following example illustrates the apportionment of the cost of covered Part B services on a departmental basis. In the example, the following assumptions are made:

(1) There are no covered services furnished in the following departments: dental, optical, and social and community services;

(2) Allocable indirect costs (e.g., medical records costs) and general and administrative costs have been distributed to departments;

(3) Unallowable costs have been excluded (e.g., research costs, unallowable costs related to capital expenditures (see § 417.242(b)(13)));

(4) Statistical data are weighted for time and complexity.

MEDICAL CENTER AID

[Example: Apportionment of allowable cost of medical services furnished directly by the HMO]

Department—(1)	Total allowable cost—(2)	Total services—(3)	Total covered services furnished enrollees who are title XVIII beneficiaries—(4)	Percent of covered services furnished enrollees who are title XVIII beneficiaries—(5)	Apportioned cost of covered services furnished to enrollees who are title XVIII beneficiaries (col. 5 × col. 2)—(6)
1. Primary care	[1] $750,000	[1] 100,000	[1] 27,000	[1] 27.00	[1] $202,500
2. Laboratory	120,000	75,000	10,000	[2] 13.33	15,996
3. X-ray	50,000	20,000	2,800	[2] 14.00	7,000
4. Mental health	100,000	12,000	1,000	[2] 8.33	8,330
5. Dental	200,000	20,000	0		
6. Optical	235,000	15,000	0		
7. Social and community	20,000	10,000	0		

MEDICAL CENTER AID—Continued

[Example: Apportionment of allowable cost of medical services furnished directly by the HMO]

Department—(1)	Total allowable cost—(2)	Total services—(3)	Total covered services furnished enrollees who are title XVIII beneficiaries—(4)	Percent of covered services furnished enrollees who are title XVIII beneficiaries—(5)	Apportioned cost of covered services furnished to enrollees who are title XVIII beneficiaries (col. 5 × col. 2)—(6)
Total	1,475,000				233,826

[1] Enrollees who are titled XVIII beneficiaries received 27,000 Part B covered services. For the 100,000 total services furnished, the primary care department incurred $750,000 total allowable costs. The following illustrates the apportionment of costs for the primary care department:

Ratio of total covered services furnished enrollees who are title XVIII beneficiaries in the primary care department to total services furnished all HMO enrollees and other patients in the primary care department: 27,000/100,000 = 27.00 percent.

The health insurance program's share of the primary care department's costs for Part B covered services furnished title XVIII beneficiaries who are enrollees of the HMO: the total allowable costs incurred by the primary care department ($750,000) × the ratio (27.00 percent) = $202,500 (see line 1, column 6).

[2] Calculations not shown. See footnote 1 of this example for methodology.

(f) *Method of apportionment of administrative and general costs of the HMO plan.* (1) Enrollment, marketing, membership, and other administrative and general costs of the HMO plan that benefit the total enrolled population of the HMO and which are not directly associated with providing medical care shall be apportioned on the basis of a ratio of enrollment of title XVIII beneficiaries to the total HMO enrollment.

(2) General management and other administrative and general costs of the HMO plan that bear a significant relationship to services furnished by the HMO shall be included in the overall costs of the HMO. These costs shall be apportioned on the basis of the percentage of the HMO's total costs (excluding the general management and other administrative and general costs of the HMO plan to be apportioned) that have been apportioned to the health insurance program by acceptable methods of apportionment set forth in this section.

(g) *Example.* The following illustrates the apportionment of the general management and other administrative and general costs of the HMO plan that bear a substantial relationship to services furnished by the HMO (described in paragraph (f)(2) of this section). These costs are apportioned on the basis of a percentage of costs (excluding the general management and other administrative and general costs of the HMO plan to be apportioned) already apportioned to the health insurance program by acceptable apportionment methods. These acceptable apportionment methods are set forth in paragraphs (a) through (d) of this section for the HMO's health services delivery components (e.g., providers of services and components furnishing physicians' services) and in paragraph (f)(1) of this section for groupings of HMO plan expense (e.g., enrollment, marketing, membership, and other administrative and general expense) apportioned on the basis of enrollment. In the example, the following assumptions are made:

1. Medical service components—direct and indirect cost:	
Medical center A	$1,475,000
Medical center B	1,500,000
Medical center C	1,525,000
	$4,500,000
2. Provider of services components—direct and indirect cost	2,500,000
3. Enrollment, marketing, membership, and other administrative and general costs of the HMO plan (not directly associated with providing medical care) that benefit the total enrolled HMO population	300,000
4. General management and other administrative and general costs of the HMO plan	600,000
5. Total	$7,900,000
6. Total enrollees	30,000
Enrollees who are title XVIII beneficiaries	3,000
Ratio of title XVIII to total enrollees (percent)	10
7. Apportionment of provider services based on established stepdown and cost finding methods (percent)	30

8. Statistical data meet the conditions for weighting set forth in paragraph (d) of this section ....

9. Allocable indirect costs (e.g., medical records) and administrative and general expense of the medical service components and provider components have been distributed to the departments of these components by acceptable cost finding and allocation methods ....

10. Unallowable costs, including administrative and general costs applicable to such unallowable costs, such as research costs and unallowable costs related to capital expenditures (see § 417.242(b)(13)), have been excluded ....

[Apportionment of Administrative and General Costs of the HMO Plan]

HMO components and expense groupings—(1)	Total cost—(2)	Apportioned cost of covered services furnished HMO enrollees who are title XVIII beneficiaries—(3)	Percentage of HMO costs apportioned for covered services furnished HMO enrollees who are title XVIII beneficiaries—(4)
1. Medical center A	$1,475,000	[1] $233,826	15.85
2. Medical center B	1,500,000	[1] 240,000	16.00
3. Medical center C	1,525,000	[1] 244,000	16.00
4. Subtotal	4,500,000	717,826	....
5. Provider of services	2,500,000	[2] 750,000	30.00
6. Subtotal	7,000,000	1,467,826	....
7. Enrollment, marketing, membership, and other administrative and general costs that benefit the total enrolled HMO population	300,000	[3] 30,000	10.00
8. Total	7,300,000	1,497,826	[4] 20.52
9. General management and other administrative and general costs	600,000	[5] 123,120	20.52
10. Total	7,900,000	1,620,946	....

[1] Apportioned on the basis of the ratio of covered Part B services provided to enrollees who are title XVIII beneficiaries to total services furnished to all enrollees of the HMO and nonenrollees on a departmental basis (see paragraphs (c) and (e) of this section).

[2] Apportioned by acceptable methods of apportionment set forth in Parts 412 and 413 of this chapter (see paragraph (h) of this section).

[3] Apportioned on the basis of a ratio of enrollment of title XVIII beneficiaries to total HMO enrollment (see paragraph (f)(1) of this section).

[4] Computed by dividing the sum of the apportioned cost of covered services furnished HMO enrollees who are title XVIII beneficiaries ($1,497,826—line 8, column 3) by the HMO's total cost, except for management and other administrative and general cost ($7,300,000—line 8, column 2).

[5] Computed by applying the percentage of HMO costs apportioned for covered services furnished HMO enrollees who are title XVIII beneficiaries, as determined in line 8, column 4 (20.52 percent), to the management and other administrative and general costs in line 9, column 2 ($600,000 times 20.52 percent = $123,120) (see paragraph (f)(2) of this section).

(h) *Other methods of allocation and apportionment.* (1) A method of apportionment or basis for allocation of costs, other than the methods prescribed in this subpart, may be used provided such method results in a more accurate and equitable apportionment of allowable costs and is justifiable from an administrative and cost standpoint. An HMO that desires to use such an alternate method must submit its request to do so to HCFA, in writing, at least 90 days prior to the beginning of the period to which the different method or basis of allocation is to be used. Once having obtained approval from HCFA to use a different method or basis of allocation, the HMO may not revert to another method without first obtaining the approval of HCFA.

(2) Where a developing HMO does not have the capability to collect the statistical and financial data required to apportion allowable costs pursuant to the requirements set forth in this section, it may, after first obtaining the approval of HCFA, use another method for apportioning or allocating allowable costs. However, the HMO must present a plan which satisfies HCFA that it will have the capability necessary to collect statistical and financial data to apply the methods of apportionment required by this subpart within a reasonable period of time, not to exceed two contract periods after the expiration of the period of its initial contract with HCFA.

[41 FR 49598, Nov. 9, 1976; 41 FR 53320, Dec. 6, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 34832, Sept. 30, 1986]

§ 417.244 Adequate financial records, statistical data, and cost finding.

(a) HMO's must maintain sufficient financial records and statistical data for proper determination of costs payable to the HMO pursuant to this subpart by the health insurance program for the covered services furnished by the HMO to its enrollees who are title XVIII beneficiaries, whether furnished directly by the HMO or under arrangements by the HMO with others. Unless otherwise provided for in this subpart, standardized definitions, accounting, statistics, and reporting practices which are widely accepted in the health care industry shall be followed.

(b) The HMO must provide adequate cost and statistical data, based on its financial and statistical records, which are capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting. However, where governmental institutions operate on a cash basis of accounting, cost data based on such basis of accounting will be acceptable, subject to apporpriate treatment of capital expenditures.

(c) Where the services of providers of services are furnished directly by the HMO, the provider of services is subject to the cost-finding and cost-reporting requirements set forth in Parts 412 and 413 of this chapter. An approved cost-finding method described in § 413.24 of this chapter must be used to determine the actual cost of covered services furnished directly by the HMO during its reporting period.

(d) Where physicians' and other Part B medical services (not furnished by a provider of services) are furnished directly by the HMO, the statistical and financial data for such services shall be reported by departments (e.g., primary care, laboratory, X-ray). Statistics shall be furnished that indicate the frequency and type of service provided, in such form and detail as prescribed by HCFA. Costs allocable to more than one department, such as medical records, shall be distributed to each such department in proportion to the benefits received by the department. Other general and administrative costs of a health services delivery components of the HMO which cannot be assigned to a specific department shall be allocated on the basis of costs already distributed or allocated to the department.

(e) Where physicians' and other Part B medical services (not furnished by a provider of services) are furnished by the HMO through arrangements, the HMO shall furnish statistical, financial, and other information with respect to such services in such form and detail as prescribed by HCFA.

(f) Accurate and sufficient detail of incurred costs, enrollment, and statistical data shall be maintained in financial and other records and shall be reported in such form and detail as required by HCFA. In the case of a separate organization or department that performs administrative services, such as centralized purchasing, accounting, data processing, etc., that benefit the HMO and the HMO's major functional components, such as a hospital, skilled nursing facility, or other activity owned by the HMO, these costs shall be allocated or distributed to each such components in reasonable proportion to the benefits received by the component. Other allocable administrative service costs that cannot otherwise be distributed shall be allocated on the basis of cost already distributed or allocated to the component (see § 417.243(f)).

[41 FR 49595, Nov. 9, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 34832, Sept. 30, 1986]

§ 417.245 Interim per capita payments.

(a) *Principle of payment.* Each month HCFA shall pay, in advance, to the HMO its interim per capita rate of payment for each individual enrolled in the HMO for whom the health insurance program is responsible for making such a payment pursuant to § 417.221. Additional lump-sum payments may be made at other times during the contract period, at the discretion of HCFA, to adjust the total amounts paid during the contract period to the level of incurred costs.

(b) *Determination of rate.* The interim per capita rate of payment is equal to the estimated per capita cost of providing covered services to title XVIII beneficiaries enrolled in the HMO, based upon types and components of costs which are reimbursable pursuant to this subpart. The interim per capita rate shall be determined annually by HCFA on the basis of the HMO's annual operating and enrollment forecast (see paragraph (e) of this section) and may be revised during the contract period as explained in paragraph (c) of this section.

(c) *Adjustments of payments.* In order to maintain the interim payments at the level of current reasonable costs, HCFA shall adjust the interim per capita rate, to the extent necessary, on the basis of adequate data supplied by the HMO in its interim estimated cost and enrollment reports or such other evidence that HCFA may have that the rate based on actual costs is more or less than the current rate. Adjustments may also be made where there is:

(1) A change in the number of enrollees in the HMO who are title XVIII beneficiaries and the per capita cost rate is affected;

(2) A material variation from the costs estimated when the annual operating budget was prepared; or

(3) A significant change in the use of covered services by enrollees in the HMO who are title XVIII beneficiaries.

(d) *Reduction in payment.* HCFA may reduce interim payments, to the extent appropriate, in the event that reports (and other data the HMO is required to submit pursuant to this subpart in order to determine the amount of payment to be made) are not furnished timely, or may take such other action as is authorized pursuant to this subpart. An interim payment reduction shall remain in effect until such time as a reasonable estimate of per capital costs can be made.

(e) *Budget and enrollment forecast.* (1) The HMO shall submit an annual operating budget and enrollment forecast, in such form and detail as HCFA may require, at least 90 days prior to the beginning of each contract period. Such forecast shall be based upon information and statistical data capable of verification where a detailed review of supporting records is required by HCFA. Such information and data include, but are not limited to, all ledgers, books, records and original evidence of costs and statistical data which pertain to the determination of reasonable cost. (See also § 417.223(b) on the enrollment forecast.)

(2) Whenever the budget and enrollment forecast is not submitted on a timely basis, HCFA may:

(i) Establish an interim per capita rate of payment (see paragraph (b) of this section) on the basis of the best available data and adjust payments based on such a rate until such time as the required reports are submitted and a new interim per capita rate can be established, or

(ii) Advise the HMO that interim payments will not be made until such time as the required reports are submitted if there is not sufficient data on which to establish an interim per capita rate of payment.

(f) *Interim cost and enrollment reports.* An HMO is required to submit interim cost reports and enrollment data on a quarterly basis in such form and manner as HCFA may prescribe. The interim cost reports of a contract period shall be submitted not later than 60 days after the close of each quarter of the HMO's contract period.

§ 417.246 Interim settlement.

(a) *Determination.* Within 30 days following the receipt of the required HMO reports, HCFA shall make an interim determination of the estimated amount payable to the HMO for the reasonable cost of covered services furnished to its enrollees who are title XVIII beneficiaries during the contract period. Such determination shall be made on the basis of the interim cost reports (see § 417.245(f)), enrollment data submitted by the HMO, and such other relevant data as HCFA finds appropriate. For this purpose, costs shall be accepted as reported, subject to later audit, unless there are obvious errors or inconsistencies.

(b) *Payment.* Any difference between the total amount of interim payments and the amount found payable on the basis of the interim determination, described in paragraph (a) of this section, shall be paid by such HMO or by HCFA, whichever is appropriate, no later than 30 days after such determination.

§ 417.247 Final settlement.

(a) *General.* Final settlement and payment of amounts due the HMO or the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall be made following the submission and review of an independently certified financial statement and supporting documents as described in paragraph (b) of this section.

(b) *Certified financial statement as basis for final settlement*—(1) *General.* The HMO shall submit to HCFA an independently certified financial statement and supporting documents, in such form and detail as HCFA may prescribe, no later than 180 days following the close of each contract period. Such statement shall include:

(i) The HMO's per capita incurred costs (based upon principles described in §§ 417.240 through 417.244) of providing covered services to its enrollees who are title XVIII beneficiaries during the contract period, including costs incurred by another organization related to the HMO by common ownership or control:

(ii) The HMO's methods of apportioning costs among enrollees who are title XVIII beneficiaries, enrollees who are not title XVIII beneficiaries, and others (nonenrollees receiving health care services on a fee-for-service or other basis), in accordance with reimbursement procedures required pursuant to this subpart (and, as applicable, Parts 412 and 413 of this chapter); and

(iii) Such information on enrollment and other data as HCFA may require.

(2) *Failure to report required financial information.* Whenever an HMO does not submit the required financial statement and supporting documents within the time specified in paragraph (b)(1) of this section, except where the HMO has requested and received an extension of time for good cause shown, such failure to report such information may be deemed by HCFA to constitute evidence of likely overpayment on the basis of which appropriate recovery of amounts previously paid or the reduction of interim payments may be made.

(c) *Final settlement.* (1) Final settlement consists of a determination by HCFA, following the submission of acceptable reports specified in paragraph (b) of this section, of total reimbursement due the HMO (which is subject to the audit provisions of this subpart) and a retroactive adjustment to bring interim payments into agreement with the reimbursable amount due the HMO. A final settlement may be made with the HMO even though a provider of services which is not owned or operated by the HMO or related to the HMO by common ownership or control and which provides services to the HMO's enrollees who are title XVIII beneficiaries has not had a final settlement with HCFA under Parts 412 and 413 of this chapter for the reasonable cost of services furnished title XVIII beneficiaries other than those enrolled in the HMO. However, HCFA must be satisfied that the costs of covered services provided the HMO's enrollees who are title XVIII beneficiaries, as shown in the reports specified in paragraph (b) of this section, are reasonable and that the interests of the health insurance program would best be served by not delaying final settlement with the HMO until there is a final settlement with the provider of services under Parts 412 and 413 of this chapter (e.g., if the provider's costs represent an insignificant amount of total reimbursement due the HMO; or if HCFA is satisfied that the provider's costs, as shown in the reports specified in paragraph (b) of this section, will not be modified, to any significant extent, by the final settlement with the provider under Parts 412 and 413 of this chapter).

(2) The retroactive adjustment is based on the required financial reports (as specified in paragraph (b) of this section) of the cost actually incurred by the HMO (in accordance with the principles of cost reimbursement in § 417.240 through § 417.244) for providing covered services to enrollees in the HMO who are title XVIII beneficiaries.

(3) The notice of amount of reimbursement by the health insurance program shall:

(i) Explain HCFA's determination regarding total reimbursement due the organization by the health insurance program for the contract period covered by the financial information specified in paragraph (b) of this section;

(ii) Relate this determination to the HMO's claimed total reimbursable costs for such period;

(iii) Explain the amount(s) and reason(s), by appropriate reference to law, regulations, and health insurance program policy and procedures, where such determination may differ from the HMO's claim; and

(iv) Inform the HMO of its right to have the determination reviewed at a hearing in accordance with Subpart R of Part 405 of this chapter.

(4) HCFA's determination (as contained in the notice of amount of reimbursement by the health insurance program) shall constitute the basis for making retroactive adjustments to any program payment made by the health insurance program to the HMO during the period to which the determination applies, including the suspending or offset of further payments to the HMO in order to recover, or to aid in the recovery of, any overpayment identified in the determination as having been made to the HMO, notwithstanding a request for a hearing on the determination which the HMO may make pursuant to Subpart R of Part 405 of this chapter. Any such suspension shall remain in effect as specified in § 405.373(a).

[41 FR 49595, Nov. 9, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 34832, Sept. 30, 1986]

PRINCIPLES OF REIMBURSEMENT FOR RISK-BASIS HMO'S UNDER TITLE XVIII

§ 417.249 Reimbursement of risk-basis HMO's—Introduction.

(a) A mature HMO (as defined in § 417.201(b)) which meets the requirements of paragraph (a) (1) or (2) of § 417.204, may elect to be reimbursed on an incentive basis for the covered services it furnishes to its enrollees who are title XVIII beneficiaries. The distinguishing characteristic of incentive reimbursement is that the total payment to the HMO for a contract period is determined by comparing the HMO's adjusted per capita incurred cost to the adjusted average per capita cost of providing covered title XVIII services (including chronic renal disease benefits) to a similar beneficiary population outside the HMO. Based on this comparison, the HMO and the health insurance program trust funds share savings up to prescribed limits, or the HMO absorbs losses. If the HMO's adjusted per capita incurred cost is less than the adjusted average per capita cost as defined in § 417.251, the difference is termed "savings" and payment of the HMO's share and the share of these savings to be paid to such trust funds is made in the manner described in § 417.252(b). If the HMO's adjusted per capita incurred cost exceeds the adjusted average per capita cost, the difference is termed "losses" and such losses are absorbed by the HMO. Losses are carried forward and offset from savings realized in later contract periods, as provided in § 417.252(c).

(b) The specific principles and procedures applicable to incentive reimbursement are discussed in §§ 417.250 through 417.254. The procedures described in § 417.245 (Interim per capita payments) are also applicable to risk-basis HMO's. Monthly interim per capita payments made by HCFA to a risk-basis HMO are determined on the same basis as those made to cost-basis HMO's and are not adjusted for estimated savings. In no case shall the interim per capita reimbursement rate of payment exceed the estimated adjusted average per capita cost.

[41 FR 49602, Nov. 9, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.250 Determining adjusted incurred cost.

HCFA uses the cost determination procedure described in this section to develop an adjusted incurred cost for the HMO.

(a) *Total reimbursable cost.* The reimbursement principles as described in §§ 417.240—417.244 are used to determine the total allowable, reimbursable, reasonable cost incurred by the risk-basis HMO for the contract period in providing covered items and services to its enrollees who are title XVIII beneficiaries except for the provisions pertaining to reinsurance costs and for the limitations on reimbursement set forth in § 417.242(b)(14).

(b) *Reinsurance.* (1) The health insurance program's share of reasonable costs for reinsurance (i.e., protection against all or part of the financial risk that the HMO is obligated to assume under its subscriber agreement with enrollees who are title XVIII beneficiaries) is allowable to the extent that the HMO incurs reinsurance costs for:

(i) Covered emergency services (§ 417.205(a)(3)(i)) furnished outside the HMO's service area (§ 417.205 (a)(1)),

(ii) Covered urgently needed services (§ 417.205 (a)(3)(ii)) furnished outside the HMO's enrollment area (§ 417.205(a)(1)),

(iii) Covered items and services, other than those described in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, furnished outside the HMO's enrollment area through arrangements (§ 417.205(a)(2)), and

(iv) Effective with contract periods beginning on or after December 1, 1976, covered items and services with allowable costs as determined under this subpart, the aggregate value of which exceeds $5,000 provided to an HMO enrollee in any contract period.

(2) If the actual cost of reinsurance cannot be readily determined for such covered items or services specified in paragraph (b)(1) of this section, which are furnished enrollees who are title XVIII beneficiaries, a reasonable estimate may be used.

(3) If a risk-basis HMO is reimbursed for reinsurance (as described in paragraph (b)(1) or (2) of this section), the HMO's allowable cost excludes any amount otherwise representing payment for such covered services delivered to its enrollees who are title XVIII beneficiaries for which the HMO is covered by reinsurance. If a risk-basis HMO does not obtain reinsurance (as described in paragraph (b)(1) or (2) of this section) and/or has a reciprocal arrangement with other HMO's for providing such covered services, the HMO is reimbursed for the reasonable cost actually incurred by the HMO for these covered services delivered to enrollees who are title XVIII beneficiaries.

(c) *Title XVIII limitations on reimbursement.* Unless otherwise specified in this subpart, the title XVIII limitations on reimbursement set forth in § 417.242(b)(14) shall not apply to services furnished to an HMO's enrollees who are title XVIII beneficiaries by a provider of services or other health care facility owned or operated by a risk-basis HMO or related to a risk-basis HMO by common ownership or control.

(d) *Adjusted incurred cost.* The reasonable costs actually incurred by the HMO under a contract pursuant to section 1876 of the Act in providing covered services to enrollees who are title XVIII beneficiaries, as determined pursuant to paragraph (a) of this section, are adjusted in order to obtain greater comparability with the adjusted average per capita cost. Adjustments to the HMO's incurred cost for the purpose of determining savings or losses (see § 417.252(a) include:

(1) *Deductibles and coinsurance.* There is deducted from the reasonable cost actually incurred by the HMO, for covered services furnished title XVIII beneficiaries enrolled with the HMO, an amount equal to the actuarial value of the deductible and coinsurance amounts which would otherwise be applicable to the covered services for which payment is being made if the title XVIII beneficiaries who received the services had not been enrolled in the HMO.

(2) *HMO option—payment to providers by intermediaries.* If the HMO has elected to have providers of servies (as defined in section 1861(u) of the Social Security Act) that are participating in the health insurance program and that furnished covered services to its enrollees who are title XVIII beneficiaries, obtain reimbursement directly from their title XVIII intermediaries (see § 417.241(d)), the reasonable cost of these covered items and services reimbursed by the intermediaries (less applicable deductibles and coinsurance), as well as intermediary administrative costs applicable to such payment, is added to the reasonable costs actually incurred by the HMO.

(3) *HMO option—payment by carriers for out-of-plan services.* If covered items and services for which the HMO is financially responsible are provided out-of-plan and are reimbursed by title XVIII carriers, the reasonable charges paid for these covered items and services (less applicable deductibles and coinsurance), as well as carrier administrative costs applicable to such payment, are added to the reasonable cost actually incurred by the HMO.

[41 FR 49602, Nov. 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 5823, Feb. 10, 1978. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.251 Determining adjusted average per capita cost.

(a) *General.* The adjusted average per capita cost, as described in section 1876(a)(3)(A)(iv) of the Act, is the amount that is compared with the HMO's adjusted per capita incurred cost to determine whether the HMO has incurred a per capita "savings" or "loss". It represents the average per capita cost, subject to appropriate actuarial adjustment, which would have been incurred by the health insurance program on behalf of enrollees of the HMO who are title XVIII beneficiaries if they had received their covered services from providers of services, physicians, suppliers, and organizations other than the HMO in the same "geographic area" (as defined in paragraph (b) of this section) served by the HMO or a "similar area" (as defined in paragraph (c) of this section). HCFA computes the adjusted average per capita cost or an estimated adjusted average per capita cost under the following circumstances:

(1) As part of the procedures for final settlement and payment with a risk-basis HMO (see § 417.254), HCFA determines the adjusted average per capita cost;

(2) For use in the interim settlement and tentative settlement with a risk-basis HMO (see § 417.253), HCFA determines an estimated adjusted average per capita cost subject to adjustment at the time of final settlement; and

(3) Upon request by the HMO, HCFA makes a preliminary estimate of the adjusted average per capita cost for the contract period or the following year, using the latest available data applicable to such an HMO. Such a preliminary estimate of the adjusted average per capita cost is computed and furnished to the HMO with the understanding that the adjusted average per capita cost retrospectively computed at the time of final settlement, using the latest available data applicable to the HMO, may be significantly different from the estimate.

(b) *Geographic area.* The geographic area used in determining the adjusted average per capita cost is normally the area or areas of residence for enrollees in the HMO who are title XVIII beneficiaries.

(c) *Similar area.* In some cases the geographic area, as defined in paragraph (b) of this section, may not be an appropriate basis of comparison because, if used, it would result in an HMO's being reimbursed significantly more or less than is reasonable for the covered services rendered. If there is substantial evidence of special characteristics that may have such results (e.g., an area that was significantly underserved and the HMO provided adequate services), HCFA may determine on an individual HMO basis that a similar area is a more appropriate geographic area for computing the adjusted average per capita cost. In such a case, HCFA selects an area similar in its major actuarial features to the HMO's geographic area, except for the special characteristics.

(d) *Computation of adjusted average per capita cost.* Before the beginning of the contract period, HCFA shall inform the HMO of the specific actuarial factors to be included in computing the adjusted average per capita cost at the time of final settlement. In computing the adjusted average per capita cost, HCFA uses the U.S. per capita incurred cost, as defined in paragraph (d)(1) of this section, modified by a number of actuarial factors, as described in paragraphs (d)(2) through (4) of this section.

(1) *U.S. per capita incurred cost.* The U.S. per capita incurred cost represents the average per capita cost, including administrative expenses reimbursed to intermediaries and carriers, incurred by the health insurance programs, as determined on an accrual basis, for covered services furnished to title XVIII beneficiaries. The U.S. per capita incurred cost is based on the determination of incurred cost used by the Office of the Actuary of HCFA, in connection with the Annual Reports of the Board of Trustees of the Social Security Trust Funds, and covers the same time period as the HMO's contract period.

(2) *Geographic index.* In computing the adjusted average per capita cost, an appropriate actuarial adjustment is made by HCFA to reflect the relative level of health insurance program expenditures for title XVIII beneficiaries in the HMO's geographic area, who are not enrolled in the HMO. This adjustment is independent of the influence of the age and sex distribution of the area's title XVIII beneficiaries. The geographic index is based on services reimbursed by the health insurance program and utilizes the most accurate and timely data available to HCFA to adapt the U.S. per capita incurred cost figure to the HMO's geographic area.

(3) *Age, sex, and disability status.* The adjusted average per capita cost is adjusted to reflect the age and sex distribution and disability status of the HMO's enrollees who are title XVIII beneficiaries, as health insurance program experience indicates differences in costs by age, sex, and disability status of such beneficiaries. Adjustments for age and sex are made for those beneficiaries age 65 and over as well as those beneficiaries under age 65 qualifying for title XVIII benefits on the basis of disability. The adjustments for age and sex of beneficiaries under age 65 include those beneficiaries qualifying for title XVIII benefits under section 226(b) or 226(e) of the Act. The adjustment factors for age and sex are based on data compiled annually by the Office of Program Policy and Research of HCFA and the distribution by age and sex for the HMO's title XVIII beneficiaries. For example, for beneficiaries 65 and over, such adjustment is comprised of separate factors for each 5 years of age by sex through age 84, plus a separate factor for all beneficiaries 85 and over by sex.

(4) *Other relevant factors.* If accurate data are available and appropriate, race, institutional status, and other relevant factors, as specified in section 1876(a)(3)(A)(iv) of the Social Security Act, are reflected in the adjusted average per capita cost computation.

[41 FR 49602, Nov. 9, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.252 Computation of the amount due to (or from) the HMO.

(a) *Determining per capita savings or losses.* HCFA determines whether the risk-basis HMO has incurred savings or losses by comparing the HMO's adjusted incurred cost (see § 417.250) to the adjusted average per capita cost (see § 417.251). In making this comparison, both the HMO's adjusted incurred cost and the adjusted average per capita cost are first converted to a monthly per capita basis. To accomplish this conversion, the HMO's adjusted incurred cost is divided by the total number of contract months for title XVIII beneficiaries who are enrollees to develop the HMO's monthly per capita adjusted incurred cost. (Total number of contract months for title XVIII beneficiaries who are enrollees is the cumulative number of such contracts, recorded as of the first day of each month, for all months included in the HMO's contract period. If more than one person is enrolled under one contract, each person is counted for a contract month.) The adjusted average per capita cost is also converted to a monthly per capita basis. A comparison is then made of the HMO's monthly per capita adjusted incurred cost and the monthly adjusted average per capita cost to determine the monthly per capita savings or losses as defined in § 417.249. This monthly per capita savings (or losses) is multiplied by the cumulative total number of contract months for title XVIII beneficiaries who are enrollees of the HMO during the contract period to determine the total amount of savings to be apportioned (or losses to be absorbed).

(b) *Apportionment of savings.* Accrued savings for each contract period shall be apportioned between the HMO and the health insurance program, following the close of such contract period, as follows:

(1) If losses for prior contract period(s) have not been offset, the provisions of paragraph (c) of this section apply.

(2) If there are no losses for prior contract period(s) to be offset, savings of up to 20 percent of the adjusted average per capita cost are apportioned equally between (i) the HMO and (ii) the health insurance program trust funds.

(3) Remaining savings in excess of 20 percent of the adjusted average per capita cost, are apportioned entirely to the health insurance program trust funds.

(c) *Carrying losses forward and offsetting losses.* If an HMO incurs losses, they are absorbed fully by the HMO. Such losses are carried forward and offset from savings realized in later contract periods as follows:

(1) Losses are offset against savings only in subsequent contract periods, i.e., not against savings in prior contract periods.

(2) Losses are offset in the order in which they are incurred, i.e., losses for earliest contract period(s) are offset first.

(3) Losses for prior contract period(s) in excess of current contract period's savings are carried forward and offset in accordance with paragraph (c)(2) of this section.

(4) If there are savings remaining after losses for prior contract periods have been offset, the remaining savings up to 20 percent of the adjusted average per capita cost are apportioned equally between (i) the HMO and (ii) the health insurance program trust funds except that remaining savings in excess of 20 percent of the adjusted average per capita cost shall be apportioned entirely to the health insurance program trust funds.

(5) If a merger is effected involving one or more risk-basis HMO's, a loss carry-over is permitted to the surviving risk-basis HMO but only to the extent that, for reporting periods prior to the effective date of the merger, the combined total losses of the one or more risk-basis HMO's that are parties to the merger exceed the combined total savings of the one or more risk-basis HMO's that are parties to the merger.

(6) In the case of HMO's that are related organizations, the losses incurred by one HMO may not be offset against the savings of another.

(7) If a risk-basis HMO subsequently exercises its option to become a cost-basis HMO, losses from prior contract period(s) are not considered an allowable cost to the cost-basis HMO.

(8) Deficits incurred by an HMO prior to the effective date of its risk-basis contract with HCFA are not carried forward nor offset against savings in contract periods subsequent to the date of the contract.

(9) If a risk-basis HMO, having a carry-over of losses, terminates its participation in the health insurance program, losses from prior contract period(s) in excess of current contract period's savings are not considered an allowable cost of either the last con-

tract period or the termination process and such a loss carry-over is not available if a successor HMO subsequently enters into an agreement to be reimbursed as a risk-basis HMO.

(d) *Computation of the amount due to (or from) the HMO for the contract period.* (1) The liability of the health insurance program, as determined by HCFA for the contract period, equals the total allowable reasonable cost actually incurred by the HMO for covered services (less deductibles and coinsurance) provided enrollees who are title XVIII beneficiaries (including those entitled on the basis of end-stage renal disease),

(i) Plus the HMO's share of savings (see paragraphs (a) and (b) of this section), or

(ii) Minus the HMO's losses (see paragraphs (a) and (c) of this section).

(2) To determine the amount due to (or from) the HMO, HCFA takes into account any previously made interim payments to the HMO as well as payments at the time of interim settlement and tentative settlement which are applicable to the same contract period. For purposes of this section, the term "interim payments to the HMO" includes all payments made by HCFA for the pertinent contract period, including monthly interim per capita payments, lump sum payments, and payments made at the time of interim settlement and tentative settlement (see § 417.253).

[41 FR 49603, Nov. 9, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.253 Interim and tentative settlements.

(a) *Interim settlement*—(1) *Determination.* Within 90 days after the close of a contract period (or not more than 30 days after the submission of adequate reports, data, and information required by HCFA if such submission occurs more than 60 days after the end of the contract period) HCFA makes a determination of the estimated amount payable to the HMO under its contract with HCFA for the contract period. Such determination is based on the estimated adjusted average per capita cost (see § 417.251), the HMO's per capita incurred allowable costs, acceptable interim cost reports, enrollment data (as recorded in HCFA records), actuarial data, and such other required data and information in such form and detail as required by HCFA and as are available. Besides the data required by § 417.244, the HMO shall maintain and submit, along with the last interim cost report for the contract period, other required data and information. Such data and information include the following:

(i) The number of beneficiaries age 65 and over enrolled in the HMO for hospital insurance and supplementary medical insurance benefits (or supplementary medical insurance benefits only) during the contract period, and their distribution by age, sex, and disability status for each subdivision in the HMO's geographic area;

(ii) The number of beneficiaries under age 65 enrolled in the HMO for hospital insurance and supplementary medical insurance benefits (or supplementary medical insurance benefits only) during the contract period and their distribution by age, sex, and disability status for each subdivision in the HMO's geographic area; and

(iii) Any other data and information for the contrast period required by HCFA, submitted at such time and in such form and detail as required by HCFA.

(2) *Payment.* On the basis of the determination as to interim settlement, 50 percent of any amounts deemed payable to the HMO or to the health insurance program trust funds shall be paid by the HMO or by HCFA, as appropriate, within 30 days of the notice of determination regarding interim settlement.

(b) *Tentative settlement.* If a final settlement is not made within one year after the HMO submits the reports specified in § 417.254(b), a tentative settlement shall be made by HCFA. At the time of tentative settlement, the determination of the estimated amount deemed payable to the HMO under its contract with HCFA for the contract period, is made on the basis of data as required by paragraph (a) of this section and additional available data. A provision of the settlement is payment by either HCFA or the HMO, as appropriate, within 30 days of the determination of any estimated amounts due, including estimated savings or losses. If appropriate, the amount of the tentative settlement is subject to adjustment at the time of final settlement.

[41 FR 49604, Nov. 9, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.254 Final settlement.

(a) *General.* Final settlement and payment of amounts due the HMO or the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall be made, following submission of an independently certified financial statement and supporting documents as described in paragraph (b) of this section.

(b) *Certified financial statement*—(1) *General.* The HMO shall submit to HCFA an independently certified financial statement and supporting documents, in such form and detail as HCFA may prescribe, no later than 180 days following the close of the contract period. Such statement shall include:

(i) The HMO's per capita incurred costs (based upon the principles described in §§ 417.240 through 417.243) of providing covered services to its health insurance beneficiaries who are enrollees during the contract year;

(ii) The HMO's methods of apportioning costs among enrollees who are title XVIII beneficiaries, enrollees who are not title XVIII beneficiaries, and others (non-members receiving health care services on a fee-for-service basis or other basis) and

(iii) Such information on enrollment and other data as HCFA may require.

(2) *Failure to submit report.* Whenever the HMO fails to submit the required adequate financial statement and supporting documents within the time specified in paragraph (b) of this section, except where the HMO has requested and received approval of an extension of time for good cause shown, such failure to report such information may be deemed by HCFA to constitute evidence of likely overpayment, on the basis of which appropriate recovery of amounts previously paid, and/or the reduction of current interim payments, may be made.

(c) *Final settlement.* The final settlement consists of a determination by HCFA, following the submission of the reports specified in paragraph (b) of this section of the amount due to the HMO as explained in § 417.252, subject to the audit provisions of this subpart, and a retroactive adjustment by HCFA of amounts paid by the HMO for the amounts determined to be due the HMO or the health insurance program trust funds, as appropriate. Payments already made, including amounts paid either by the HMO or by HCFA as a result of the interim settlement (see § 417.253(a)) and tentative settlement (see § 417.253(b)), are brought into agreement with the amount due to (or from) the HMO, in accordance with the provisions of § 417.252. A final settlement may be made with the HMO even though a provider of services which is not owned or operated by the HMO or related to the HMO by common ownership or control and which provides services to the HMO's enrollees who are title XVIII beneficiaries has not had a final settlement with HCFA under Parts 412 and 413 of this chapter for the reasonable cost of services furnished title XVIII beneficiaries other than those enrolled in the HMO. However, HCFA must be satisfied that the costs of covered services provided the HMO's enrollees who are title XVIII beneficiaries, as shown in the reports specified in paragraph (b) of this section, are reasonable and that the interests of the health insurance program would best be served by not delaying final settlement with the HMO until there is a final settlement with the provider of services under Parts 412 and 413 of this chapter (e.g., if the provider's costs represent an insignificant amount of total reimbursement due the HMO; or, if HCFA is satisfied that the provider's costs, as shown in the reports specified in paragraph (b) of this section, will not be modified, to any significant extent, by the final settlement with the provider under Parts 412 and 413 of this chapter). HCFA's determination (as contained in a notice of health insurance reimbursement) and retroactive adjustment are explained in paragraphs (c)(1) and (2) of this section.

(1) The notice of health insurance program reimbursement shall:

(i) Explain HCFA's determination regarding total health insurance program reimbursement due the organization for the contract period covered by the reports specified in paragraph (b) of this section, including an explanation of the computation of savings or losses;

(ii) Relate this determination to the HMO's claimed total reimbursable costs for such period;

(iii) Explain the amount(s) and reason(s), by appropriate reference to law, regulations, and health insurance program policy and procedures, if such determination of reimbursable cost may differ from the HMO's claim;

(iv) Inform the HMO of its right to have the determination reviewed at a hearing in accordance with Subpart R of Part 405 of this chapter.

(2) HCFA's determination (as contained in the notice of health insurance program reimbursement) shall constitute the basis for making retroactive adjustments to any health insurance program payments made to the HMO during the period to which the determination applies.

(3) HCFA may suspend or offset further payments to the HMO in order to recover, or to aid in the recovery of, any overpayment identified in the determination as having been made to the HMO, notwithstanding a request for a hearing on the determination which the HMO may make pursuant to Subpart R of Part 405 of this chapter. Any such suspension shall remain in effect as specified in § 405.373(a).

(d) *Interest.* In order that neither the HMO nor the health insurance program trust funds gain from excessive delay in final settlement (see paragraph (c) of this section), interest is charged on amounts payable if payment by HCFA or the HMO, as determined by the final settlement, takes place more than 90 days after the submission of an acceptable certified financial statement and supporting documents. Such interest, which accrues on amounts outstanding and unpaid beginning with the 91st day following the submission of such reports and continuing up to, but not including, the date such amounts are paid, is computed at a rate equal to the average rate of interest payable on obligations of the Federal Government issued on such 91st day for purchase by such trust funds.

[41 FR 49604, Nov. 9, 1976; 41 FR 53320, Dec. 6, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985, and amended at 51 FR 34832, Sept. 30, 1986]

§ 417.256 Beneficiary appeals.

(a) *Definition of enrollee.* Unless otherwise indicated, the term "enrollee" as used in §§ 417.256—417.263, means an HMO enrollee who is a beneficiary under title XVIII of the Social Security Act.

(b) *General.* (1) Sections 417.256—417.263 establish procedures for the presentation and resolution of initial determinations, reconsiderations, hearings, Appeals Council reviews, court reviews, and finality of decisions which are applicable only in matters arising under section 1876 of the Social Security Act, as amended. The grievance procedures established under section 1301(c) of the Public Health Service Act (42 FR 29400) apply to all complaints that do not involve initial determinations.

(2) The appeals procedure pertains to disputes involving:

(i) Initial determinations (see § 417.258) with which the enrollee is dissatisfied (i.e., the enrollee has received items or services for which he is held liable by the HMO); or

(ii) Requests for services which may be paid for under title XVIII of the Act and which the HMO has refused to provide or arrange for and which have not been provided elsewhere.

(3) Any determinations regarding items or services which were furnished by the HMO, either directly or through arrangement, for which the enrollee is not liable are, therefore, not subject to appeal. Services excluded from coverage under title XVIII of the Act and recognized as such in the contract between the HMO and the enrollee by their inclusion in a supplemental plan (see § 417.222(a)) or otherwise, are subject

only to a grievance procedure. (See section 1301(c) of the Public Health Service Act.) Physicians and other individuals who are furnishing items or services under arrangements with an HMO have no right of appeal under this subpart. The provisions of Subpart J of 20 CFR Part 404 dealing with representation of parties under title II of the Act are, unless otherwise provided in this subpart, also applicable to matters arising under section 1876 of the Act.

(c) *Responsibility for establishing appeal procedures.* (1) The provisions of this subpart apply equally to all beneficiaries under title XVIII of the Act who are enrollees in an HMO, regardless of the method of claims processing adopted by the particular HMO. The HMO is responsible for establishing and maintaining the appeals procedures which are specified within this subpart.

(2) If, however, a carrier or intermediary processes the claims for the HMO's enrollees, that carrier or intermediary:

(i) Is acting in the place of the HMO (except with regard to initial determinations as specified in § 417.258(a)(4)); and

(ii) Conducts the appeals procedures specified in this subpart, except that § 417.259(h)(1)(ii) shall not apply to that carrier or intermediary.

(d) *Written description of appeals procedure.* It is the responsibility of each HMO to ensure that all enrollees who are beneficiaries under title XVIII of the Act are informed in writing of the appeals procedures which are available to them.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 5827, Feb. 10, 1978. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.258 Initial determinations.

(a) *HMO, intermediary, or carrier actions which are initial determinations.* For the purpose of this subpart, an initial determination made by an HMO, or intermediary or carrier acting for the HMO, with respect to the rights of an enrollee who is a beneficiary under title XVIII of the Act includes, in addition to determinations related to services for which benefits under title XVIII of the Act may be payable, rendered by the HMO, any determination with respect to the following:

(1) Reimbursement for emergency services as defined in § 417.205(a)(3)(i);

(2) Reimbursement for urgently-needed services as defined in § 417.205(a)(3)(ii), furnished to an enrollee during a period of temporary absence from the geographic area serviced by the HMO;

(3) Any other health services which the enrollee believes to be covered under title XVIII of the Act which is rendered by a physician, supplier, or provider of services other than the HMO and which the enrollee believes should have been provided or arranged for or reimbursed by the HMO;

(4) The HMO's declination to provide services which the enrollee believes should be provided or arranged for by the HMO and which the enrollee has not received outside the HMO;

(5) The HMO's failure to notify the enrollee, in accordance with paragraph (b) of this section, of its determination within 60 days of the request to provide, arrange for, or reimburse for services shall constitute an adverse initial determination which may be appealed.

(b) *Notice of adverse initial determination.* In any case in which an HMO, intermediary, or carrier makes a partially or fully adverse determination involving a request for payment or an HMO refuses to provide or arrange for requested services with respect to the enrollee under paragraph (a) of this section, regardless of the amount in controversy, the HMO, intermediary, or carrier, as applicable, shall notify the enrollee in writing within 60 days of such enrollee's request for payment or services. Such notice to the enrollee, or his representative, shall state in detail the basis for the determination. Such written notice shall also inform the enrollee of his right to reconsideration.

(c) *Parties to the initial determination.* The parties to the initial determination are the enrollee or an assignee (i.e., a physician who accepts assignment for services rendered to enrollees, which are not covered by the plan of the HMO), or the enrollee's representative (or if the enrollee is deceased, the representative of such enrollee's estate), or any other entity determined to have an appealable interest in the proceeding.

(d) *Effect of initial determination.* The initial determination shall be final and binding upon the party or parties to such determination, or if such party is deceased, upon the representative of such individual's estate, unless the determination is reconsidered in accordance with § 417.259 or is revised in accordance with § 417.263.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.259 Appeals: Reconsideration.

(a) *General.* An enrollee, his authorized representative (or, if an enrollee is deceased, the representative of such enrollee's estate), or any party to an initial determination as described in § 417.258(c) who is dissatisfied with an initial determination as described in § 417.258(a) may request a reconsideration of such determination in accordance with paragraph (b) of this section regardless of the amount in controversy.

(b) *Place and method of filing request for reconsideration.* A request for reconsideration by an enrollee or his representative is to be made in writing and filed with the HMO, intermediary, or carrier which made the initial determination, at an office of the Social Security Administration, or, in the case of a qualified railroad retirement beneficiary (see § 406.10), at an office of the Railroad Retirement Board. The request may be made on a specific form designated by the Social Security Administration or by any written means.

(c) *Time of filing request for reconsideration.* The request for reconsideration shall be filed within 60 days after the date of receipt of notice of the initial determination, unless such time is extended as specified in paragraph (d) of this section. For purposes of this section, the date of receipt of notice of the initial determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

(d) *Extension of time to request reconsideration.* If a party to an initial determination, or his representative, desires to file a request for reconsideration after the time for filing such request specified in paragraph (c) of this section has passed, such party or representative may file a petition with the HMO, intermediary, carrier, the Health Care Financing Administration, or, in the case of a qualified railroad retirement beneficiary, at an office of the Railroad Retirement Board, for an extension of time for the filing of such request. Such petition shall be in writing and shall state the reasons why the request for reconsideration was not filed within the required time. For good cause shown, the HMO, intermediary, or carrier may extend the time for filing the request for reconsideration.

(e) *Parties to the reconsideration.* The parties to the reconsideration shall be the persons or entities who were parties to the HMO's, intermediary's, or carrier's initial determination as described in § 417.258(c) and any other person or entity whose rights with respect to the initial determination which is being reconsidered may be affected by such reconsideration.

(f) *Withdrawal of request for reconsideration.* A request for reconsideration may be withdrawn by the enrollee or his representative who filed the request provided the withdrawal is made in writing and filed with the HMO, intermediary, carrier, the Health Care Financing Administration, or, in the case of a qualified railroad retirement beneficiary, at an office of the Railroad Retirement Board.

(g) *Opportunity to submit evidence.* The parties to the reconsideration shall have a reasonable opportunity to submit written evidence and contentions as to facts or law relative to the issue in dispute. The parties may present evidence in person.

(h) *Reconsideration determination.* The first step in the reconsideration of an initial determination shall be undertaken by the HMO, intermediary, or carrier which adjudicated the claim initially, except that where the provision of services has been refused, the

HMO will conduct the reconsideration in paragraph (h)(1) of this section. The HMO, intermediary, or carrier shall thoroughly review such initial determination made under § 417.258(a), the evidence and findings upon which such determination was based, and any additional evidence submitted to the HMO, intermediary, carrier, or the Health Care Financing Administration. However, such review shall not be made by any person who made, or assisted in making, the initial determination.

(1) *Reconsideration by an HMO.* Where the HMO adjudicates the claim initially or has refused to provide or arrange for requested services, the following procedure should be followed at the reconsideration level:

(i) *If HMO can make a favorable determination.* If the HMO can make a completely favorable determination in regard to the enrollee, the HMO shall revise the initial determination accordingly;

(ii) *If HMO recommends that determination be affirmed.* If the HMO recommends that the initial determination be affirmed, in whole or in part, the HMO shall prepare a written explanation of its recommendation and forward the entire case file to the Health Care Financing Administration. The Health Care Financing Administration shall review such file and any additional evidence found to be necessary, and shall make a determination affirming or revising, in whole or in part, such initial determination.

(2) *Reconsideration by an intermediary or carrier.* In those cases where an intermediary or carrier initially adjudicated the claim for the HMO, the reconsideration determination will be made by the intermediary or carrier, as applicable. Whether favorable to the beneficiary or not, it shall be a final and binding determination in accordance with paragraph (j) of this section.

(i) *Notice of reconsideration determination.* Written notice of the reconsideration determination shall be mailed to the parties to the reconsideration. The notice shall explain the basis of the reconsideration determination and shall advise the beneficiary of his right to a hearing by an administrative law judge if the amount in controversy is $100 or more. The notice shall also indicate the place and manner of requesting a hearing and the time limit during which a hearing must be requested (see § 417.260(c)).

(1) Such notice will be mailed by the HMO in those cases in which the HMO fully reverses its initial determination, and by the processing intermediary, carrier, or the Health Care Financing Administration in every case in which such organization makes the reconsideration determination. A copy of the determination shall be sent to the Health Care Financing Administration.

(2) In those cases processed by the HMO in which the initial determination is affirmed, or partially affirmed, the Health Care Financing Administration will mail notice of the reconsideration determination to the parties thereto and a copy of the notice shall be sent to the HMO.

(j) *Effect of reconsideration determination.* The reconsidered determination shall be final and binding upon all parties to the reconsideration unless a request for hearing is filed within 60 days after the date of receipt of notice of the reconsidered determination by such parties or unless the reconsideration determination is revised upon reopening in accordance with the provisions of § 417.263, or unless the expedited appeals process is used in accordance with § 405.718. For purposes of this section, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[41 FR 9311, Mar. 4, 1976, as amended at 41 FR 47918, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.260 Appeals: Hearing.

(a) *General.* Sections 404.917–404.940 of 20 CFR Part 404 (dealing with the conduct of hearings) are, unless otherwise provided in this subpart, also applicable to hearings arising under this subpart.

(b) *Right to hearing.* An enrollee or any other party as described in

§ 417.258(c) or § 417.259(e), with the exception of an HMO, has a right to a hearing before the Secretary regarding any initial determination made under § 417.258 for either Part A or Part B services if:

(1) Such initial determination has been reconsidered by the Health Care Financing Administration (unless the initial determination was fully reversed by the HMO, in accordance with § 417.259), or by an intermediary, or carrier;

(2) The enrollee, or party, was a party to the initial or reconsideration determination;

(3) The enrollee, his representative, or the party or his representative has filed a written request for a hearing in accordance with the procedure described in paragraphs (c) and (d) of this section; and

(4) The amount in controversy is $100 or more. (The amount in controversy, which can include any combination of Part A and Part B services, is to be computed in accordance with § 405.740 for Part A services and § 405.820(b) for Part B services. Where the basis for the appeal is the refusal of services, the projected value of such services shall be utilized in computing the amount in controversy.)

(c) *Place of filing request for hearing.* The request shall be made in writing at the HMO, an office of the processing intermediary or carrier, an office of the Social Security Administration or, in the case of a qualified railroad retirement beneficiary, an office of the Railroad Retirement Board.

(d) *Time limit for filing request for hearing.* Any request for hearing must be filed within 60 days after the date of receipt of notice of the reconsidered determination to the enrollee, except when the time is extended by a presiding officer as provided in 20 CFR 404.954(a). For purposes of this section, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

(e) *Parties to a hearing.* The parties to a hearing shall be the parties to the reconsideration determination and any other person whose rights with respect to the reconsideration determination might be affected. The HMO shall also be made a party to any such hearing; however, the HMO does not have a right to request a hearing. Fees for any services rendered by a representative appointed on behalf of the HMO shall not be subject to the provisions of section 206 of the Social Security Act.

(f) *Dismissal of request for hearing: Amount in controversy less than $100.* The determination as to whether the amount in controversy is $100 or more, qualifying the enrollee for a hearing, shall be made by the administrative law judge. The administrative law judge shall dismiss the request for hearing if such request plainly shows that less than $100 is in controversy. If a hearing is held and the administrative law judge finds that the amount in controversy is less than $100, he shall dismiss the request for hearing and will not rule on the substantive issues involved in the appeal.

[41 FR 9311, Mar. 4, 1976, as amended at 41 FR 47918, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.261 Appeals Council review.

Provisions regarding Appeals Council review which are contained in 20 CFR 404.942 shall apply to the HMO appeals process. The HMO which is a party to a hearing, as well as any other party, has a right to request Appeals Council review of the administrative law judge's decision or dismissal.

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.262 Court review.

An enrollee or the HMO shall be entitled to judicial review:

(a) Of the decision of an administrative law judge if the Appeals Council has denied the enrollee's or the HMO's request for review, and the amount in controversy is $1,000 or more, or

(b) Of a decision by the Appeals Council when that is the final decision of the Secretary and the amount in controversy is $1,000 or more. The civil action is to be filed in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for the procedure for filing such action).

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.263 Time period for reopening initial, revised, or reconsideration determinations and decisions or revised decisions of an administrative law judge or the Appeals Council.

An initial, revised, or reconsideration determination made by an HMO, an intermediary or carrier, or the Health Care Financing Administration or a decision or revised decision of an administrative law judge or of the Appeals Council, with respect to a party's rights under section 1876 of the Act, may be reopened in accordance with the provisions of § 405.750 (a), (b), and (c).

[41 FR 9311, Mar. 4, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.265 Health maintenance organizations contract appeals; determinations and appeals procedures.

(a) The provisions contained in this section and §§ 417.266 through 417.292 shall govern the procedures for making and reviewing determinations with respect to whether:

(1) An organization is eligible to enter into a contract with the Secretary under which such organization would qualify for participation as a health maintenance organization (hereinafter referred to as an "HMO") within the meaning of section 1876 of the Social Security Act,

(2) The Secretary's agreement with the HMO should be terminated for cause, pursuant to section 1876 of such Act, and

(3) The Secretary's agreement with the HMO should not be renewed.

(b) Any organization dissatisfied with an initial determination that it is ineligible to enter into a contract with the Secretary as an HMO under section 1876 of the Social Security Act may request a reconsideration of that determination (see § 417.270) and, if dissatisfied with the reconsidered determination, may request a hearing. An organization which has a contract with the Secretary to participate as an HMO is entitled to a hearing if it is dissatisfied with the Secretary's initial determination to terminate the contract as specified in § 417.266. In addition, any such organization is, under certain circumstances, also entitled to a hearing if it is dissatisfied with the Secretary's initial determination not to renew the contract (see § 417.266(c)).

(c) To be a participating HMO, eligible for payment, an HMO must be in compliance with title VI of the Civil Rights Act of 1964 and must enter into a contract with the Secretary under § 417.228. The provisions of this Subpart B do not govern in any respect the adjudication of issues related to the compliance of an HMO with Title VI of the Civil Rights Act of 1964, or the implementing regulation (45 CFR Part 80) promulgated by the Secretary of Health and Human Services.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.266 Initial determinations.

The Secretary shall make an initial determination with respect to:

(a) Whether an organization which has applied to enter into a contract with the Secretary under section 1876 of the Social Security Act (§ 417.228) is eligible to enter into such a contract;

(b) The termination of a contract with an HMO because the HMO:

(1) Has failed substantially to carry out the terms of the contract entered into pursuant to § 417.228, or

(2) Is carrying out the contract in a manner which is inconsistent with the efficient and effective administration of section 1876 of the Social Security Act, or

(3) No longer meets the applicable conditions necessary to qualify as an HMO under section 1876 of such Act (§ 417.228);

(c) The nonrenewal of a contract with an HMO, but only if such nonrenewal is for a reason stated in paragraph (b)(1), (2), or (3) of this section.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.267 Notice of initial determination.

(a) Written notice of an initial determination specified in § 417.266(a) shall be mailed to the organization filing the request for such determination and specifically advise the organization:

(1) As to whether it is eligible for participation as an HMO in the health insurance program; and

(2) If not so eligible, the reasons why the organization is ineligible to participate in the program.

(b) Written notice of an initial determination specified in § 417.266(b) shall be mailed to the HMO at least 90 calendar days before the effective date of such determination.

(c) Written notice of an initial determination specified in § 417.266(c) shall be mailed to the HMO at least 90 calendar days before the end of the contract period.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.268 Effect of initial determination.

The initial determination shall be final and binding upon the parties to the determination unless it is reconsidered in accordance with § 417.274 (in the case of a determination described in § 417.267(a)) or revised in accordance with § 417.291, or a request for hearing is filed (in the case of a determination described in § 417.266 (b) or (c)).

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.269 Administrative actions which are not initial determinations.

Administrative actions which shall not be considered initial determinations under any provision of the regulations in this subpart include, but shall not be limited to, the following:

(a) The refusal of the Secretary to renew a contract with an HMO where the reasons for such refusal are not among the causes specified in paragraph (b)(1), (2), or (3) of § 417.266 (e.g., a refusal to renew because the HMO no longer complies with title VI of the Civil Rights Act of 1964).

(b) The finding by the Secretary that an HMO is not eligible to enter into a risk-sharing contract as specified in section 1876(i)(2)(A) of the Social Security Act.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.270 Reconsideration; right to reconsideration; time and place of filing request for reconsideration.

Any organization which is dissatisfied with an initial determination (§ 417.266(a)) that it is ineligible to enter into a contract with the Secretary under section 1876 of the Social Security Act (§ 417.228) may request the Secretary to reconsider such determination. The Secretary shall reconsider an initial determination if a written request for reconsideration is filed by the organization within 60 calendar days after the date of receipt of the notice of initial determination (§ 417.267), or later if the time for filing is extended (§ 417.272). For purposes of this section, the date of receipt of the notice of initial determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary. The request for reconsideration is to be filed with the Medicare Bureau or with any other office of the Department of Health and Human Services.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.271 Proper party for filing request for reconsideration.

Only an authorized official of the organization which was a party to an initial determination may file the request for reconsideration of such determination (§ 417.270).

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.272 Extension of time to request reconsideration.

If a party to an initial determination desires to file a request for reconsideration after the time for filing has passed (§ 417.270), such party may file a petition with the Secretary for an extension of the time. The petition shall be in writing and shall state the reasons why the request for reconsideration was not filed within the required time. For good cause shown, the Secretary may extend the time for filing a request for reconsideration.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.273 Withdrawal of request for reconsideration.

A request for reconsideration may be withdrawn at any time prior to the mailing of notice of the reconsidered determination (see § 417.276) if a written request for withdrawal is filed with the Secretary by the organization which filed the request for reconsideration and if the Secretary approves the request for withdrawal.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.274 Reconsidered determination.

When a request for reconsideration has been filed (§ 417.270), the Secretary shall reconsider the initial determination in question and the findings on which the initial determination is based. The Secretary shall make a reconsidered determination, affirming or reversing the initial determination (§ 417.266).

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.275 Submission of evidence.

The Secretary shall accept in evidence any documents or written statements which are relevant and material to the matters at issue and which are submitted within a reasonable time after the filing of a request for reconsideration. The reconsidered determination shall be based on the evidence considered in making the initial determination and whatever other written evidence may be submitted prior to the time of the reconsidered determination, even taking into account facts relating to the status of the organization subsequent to the initial determination.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.276 Notice and effect of reconsidered determination.

(a) *Notice of reconsidered determination.* Written notice of the reconsidered determination (§ 417.274):

(1) Shall be mailed to the organization concerned;

(2) Shall contain findings with respect to whether the organization is eligible to enter into a contract with the Secretary under section 1876 of the Social Security Act (§ 417.228);

(3) Shall contain a statement of the reasons for the determination; and

(4) Shall inform the organization of its right to a hearing (§ 417.277) if it is dissatisfied with the reconsidered determination.

(b) *Effect of reconsidered determination.* The reconsidered determination shall be final and binding upon the parties to the determination unless it is revised in accordance with § 417.291, or a hearing is requested in accordance with § 417.277.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.277 Hearing; right to hearing; time and manner of filing request for hearing.

(a) *Right to hearing.* An organization which has been determined in a reconsidered determination to be not eligible to enter into a contract with the Secretary under section 1876 of the Social Security Act (§ 417.228), shall be entitled to a hearing with respect to such determination. Likewise, an HMO whose contract with the Secretary has been terminated or has not been renewed as a result of an initial determination of the Secretary as provided in § 417.266(b) or (c) shall be entitled to a hearing with respect to that initial determination.

(b) *Time and manner of filing request for hearing specified in paragraph (a) of this section.* The request for a hearing specified in paragraph (a) of this section shall be in writing and filed by an authorized official of the organization or HMO, as the case may be, which was the party to the reconsidered determination (in the case of a determination under § 417.266(a)) or the initial determination (in the case of a determination under § 417.266(b) or (c)). The request must be filed within 60 calendar days after the date of receipt of the notice of reconsidered or initial determination, as the case may be, unless such time is extended as provided in § 417.272 or in paragraph (d) of this section. For purposes of this section, the date of receipt shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary. The request for a hearing is to be filed with the Medicare Bureau or with any other office of the Department of Health and Human Services.

(c) *Time and manner of filing request for hearing with respect to certain revised determinations.* A request for a hearing with respect to a revised determination provided for in § 417.291, must be filed within 60 calendar days after the date of receipt of written notice of a revised determination, by the organization which is the party to such determination.

(d) *Exception to time of filing request for hearing.* For good cause shown, the 60-day period referred to in paragraphs (b) and (c) of this section may be extended.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.278 Postponement of effective date of initial determination.

Where a request for a hearing with respect to a determination provided for in § 417.266(b) or (c) is timely filed:

(a) The effective date of the initial determination to terminate a contract with the HMO shall be postponed until a decision is rendered by the hearing officer;

(b) The contract with the HMO may be extended at the end of a contract period, in the case of an initial determination not to renew the contract, but only if prior to the end of the contract period the Secretary finds that an extension of the contract will be consistent with the purposes of section 1876 of the Social Security Act. (Where such a finding is made the contract may be extended only for such period as the Secretary and HMO shall mutually agree.)

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.279 Parties to the hearing.

The party(ies) to the hearing on an appeal filed pursuant to § 417.277 shall be:

(a) The organization which was a party to the reconsidered determination (see § 417.270) or the HMO which was a party to the initial determination (in the case of such a determination specified in § 417.266(b) or (c));

(b) At the discretion of the hearing officer, any interested party(ies) who makes a showing that his (their) rights may be prejudiced by the decision to be rendered at the hearing; and

(c) The Medicare Bureau representing the Secretary.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.280 Hearing officer.

Any hearing provided for in § 417.277 shall be conducted by a hearing officer designated by the Secretary.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.281 Disqualification of hearing officer.

A hearing officer shall not conduct a hearing in any case in which he is prejudiced or partial with respect to any party, or if he has an interest in the matter before him. Notice of any objection with respect to the hearing officer who will conduct the hearing shall be made by the objecting party at his earliest opportunity. The hearing officer shall consider such objection and shall, at his discretion, withdraw. If the hearing officer withdraws, the Secretary shall designate another hearing officer to conduct the hearing. If the hearing officer does not withdraw, the objecting party may present his objections to the Secretary at any time prior to the issuance of a decision. The Secretary shall review the request and take appropriate action.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.282 Location of hearing.

(a) *Time and place.* The hearing officer shall fix a time and place for the hearing reasonably convenient to the requesting party and not inconsistent with the public interest.

(b) *Adjournment or postponement.* The hearing officer may, for a good and sufficient reason, fix a new time or place for the hearing; he may change the time and place for the hearing or adjourn the hearing on his own motion upon reasonable notification to the parties.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.283 Notice of hearing.

The notice of hearing shall include notice of the time and place of the hearing; information as to the specific issues to be determined; and the matters on which findings shall be made and conclusions shall be reached. The notice shall also contain sufficient information about the hearing procedure (including the party's right to representation) for effective preparation for the hearing.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.284 Conduct of hearing.

(a) *General.* Hearings shall be open to the parties and to the public. The hearing officer shall inquire fully into the matters at issue and shall accept in evidence the testimony of witnesses and any documents which are relevant and material to such matters. The parties shall be provided an opportunity to enter any objection to the inclusion of any document. The order in which evidence and allegations shall be presented and the procedure at the hearing, except as this subpart otherwise expressly provides, shall be at the discretion of the hearing officer and of such nature as to afford the parties a proper hearing.

(b) *Evidence.* Evidence may be accepted at the hearing even though inadmissible under rules of evidence applicable to court procedures. The hearing officer shall rule on the admissibility of evidence.

(c) *Witnesses.* The hearing officer may examine the witnesses and shall allow the parties or their representatives to do so. Parties to the proceedings may also cross-examine witnesses.

(d) *Discovery.* Prehearing discovery shall be permitted upon timely request of a party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the hearing officer. The hearing officer's order on all discovery matters shall be final.

(e) *Prehearing.* If, in the discretion of the hearing officer, the purpose of defining the issues more clearly would be served, the hearing officer may schedule a prehearing conference.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.285 Record of hearing.

A complete record of the proceedings at the hearing shall be made and transcribed in all cases. It shall be made available to the parties upon request. The record shall not be closed until a decision (see § 417.287) has been issued.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.286 Authority of hearing officer.

The hearing officer in exercising his authority must comply with all the provisions of title XVIII of the Social Security Act and regulations issued thereunder as well as with general instructions issued by the Health Care Financing Administration in implementing such Act and regulations.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.287 Hearing decision and notice.

The hearing officer shall render a decision in writing based on the evidence in the record. In such decision he shall cite applicable law, regulations, and Health Care Financing Administration general instructions as well as findings on all the matters at issue in the hearing. A copy of the decision shall be provided all parties to the hearing.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.288 Effect of hearing decision.

The hearing decision provided for in § 417.287 shall be final and binding upon all parties to the hearing unless it is reopened and revised in accordance with § 417.291.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.289 Appointment of representative.

A party may appoint as its representative at the proceedings conducted in accordance with § 417.284 any individual except an individual disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.290 Authority of representative.

A representative appointed by a party may accept or give on behalf of the party he represents any request or notice relative to any proceeding affecting such party. A representative shall be entitled to present evidence and allegations as to facts and law in any such proceeding and to obtain information with respect to a request for hearing made in accordance with § 417.277 to the same extent as the party he represents. Notice to a party of any action, determination, or decision which is sent to the representative of the party shall have the same force and effect, as if it had been sent to the party represented.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.291 Reopening of initial or reconsidered determination and decision of a hearing officer.

(a) *Initial or reconsidered determination.* An initial or reconsidered determination which is unfavorable to one or more parties to such determination and is otherwise final (see § 417.268 and § 417.276) may be reopened and revised by the Secretary upon his own motion within one year of the date of the notice of determination.

(b) *Decision of a hearing officer.* A decision of a hearing officer which is unfavorable to one or more of the parties to the hearing identified in § 417.279(a) or (b) and is otherwise final (see § 417.288) may be reopened and revised by the hearing officer upon his own motion within one year of the date of the notice of the decision or by another hearing officer designated by the Secretary if the hearing officer who issued the decision is unavailable.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

§ 417.292 Notice of reopening and revision.

(a) *Notice.* When any determination or decision is reopened as provided in § 417.291, notice of such reopening shall be mailed to the parties to such determination or decision at their last known addresses. A notice of revision, following a reopening of a determination or a decision, shall be mailed to the parties and shall state the basis or reasons for the revised determination or revised decision.

(b) *Effect of revised determination.* The revision of a determination shall be binding upon the parties thereto unless a party files a written request for a hearing with respect to a revised determination.

[41 FR 39308, Sept. 15, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 50 FR 1345, Jan. 10, 1985]

Subpart C—Health Maintenance Organizations and Competitive Medical Plans

Source: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.400 Basis and scope.

(a) *Statutory basis.* The regulations in this subpart implement section 1876 of the Act as amended by section 114 of Pub. L. 97-248. Section 1876 of the Act authorizes Medicare payments to HMOs and competitive medical plans (CMPs) through contracts under which the HMOs and CMPs are reimbursed for furnishing covered services to Medicare beneficiaries.

(b) *Scope.* This subpart sets forth the requirements an entity must meet in order to enter into a contract with HCFA as an HMO or CMP to be reimbursed, through capitation payments, for services furnished to Medicare beneficiaries who are enrolled with the HMO or CMP. It also specifies the principles that apply for each of the two methods for reimbursing HMOs and CMPs: reimbursement on a risk basis and reimbursement on a reasonable cost basis.

§ 417.401 Definitions.

As used in this subpart, unless the context indicates otherwise—

Adjusted average per capita cost (AAPCC) means an actuarial estimate made by HCFA in advance of an organization's contract period that represents what the average per capita cost to the Medicare program would be for each class of the organization's Medicare enrollees if they had received covered services other than through the organization in the same geographic area or in a similar area.

Adjusted community rate (ACR) is the equivalent of the premium that a risk organization would have charged to Medicare enrollees independently of Medicare payments using the same rates as charged to non-Medicare enrollees if the benefit package was limited to covered Medicare services.

Arrangement or arrangements means a written agreement executed between an eligible organization and another entity in which the other entity agrees to furnish specified services to Medicare enrollees of the organization, but the organization retains responsibility for those services. Under an arrangement, Medicare payment to the organization discharges the beneficiary's obligation to pay for the service.

Benefit stabilization fund means a fund established by HCFA at the request of an eligible organization with a new risk contract to withhold a portion of the per capita payments available to the organization for payment in a subsequent contract period for the purpose of stabilizing fluctuations in the availability of the additional benefits provided by the organization to its Medicare enrollees.

Current demonstration project Medicare enrollee means an individual who, on the effective date of these regulations, is—

(a) Enrolled with an HMO or CMP that is furnishing services pursuant to an existing demonstration project; and

(b) Entitled to benefits under part A and B of Medicare or enrolled for Part B only.

Current nonrisk Medicare enrollee means—

(a) An individual who, with respect to an eligible organization that has an existing cost contract, is enrolled with that organization on the effective date of these regulations, and is entitled to benefits under Parts A and B of Medicare or is enrolled in Part B only; and

(b) Includes Medicare enrollees who disenroll and later reenroll in the same eligible organization.

Current risk Medicare enrollee means an individual who, on the effective date of these regulations, is—

(a) Enrolled with an HMO having an existing risk-sharing contract; and

(b) Entitled to benefits under Parts A and B of Medicare or enrolled in Part B only.

Eligible organization or *organization* means a public or private entity that is either an HMO or a CMP and meets all the applicable requirements of section 1876(b) of the Act. (See § 417.407.)

Emergency services means covered inpatient or outpatient services that are furnished by an appropriate source other than the organization and—

(a) Are needed immediately because of an injury or sudden illness, and

(b) The time required to reach the organization's providers or suppliers (or alternatives authorized by the organization) would have meant risk of permanent damage to the patient's health.

These services are considered to be emergency services as long as transfer of the enrollee to the organization's source of health care or designated alternative is precluded because of risk to the enrollee's health or because transfer would be unreasonable, given the distance involved in the transfer and the nature of the medical condition.

Enrollee means an individual who is enrolled in an HMO or a CMP to receive health care services on a prepaid capitation basis.

Entity with an existing cost contract means an entity that, on the effective date of these regulations, does not have in effect an existing risk contract or an existing demonstration project and—

(a) Has in effect a contract that is entered into under section 1876 of the Act that was in effect prior to the effective date of these regulations (that is, a cost contract under Subpart B of this part); or

(b) Is reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act.

Entity with an existing risksharing contract means an entity that, on the effective date of these regulations, has in effect a contract entered into under section 1876(i)(2)(A) of the Act as in effect prior to the effective date of these regulations (that is, a risk-sharing contract under Subpart B of this part).

Existing demonstration project means a demonstration project under section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 (note)), relating to the provision of services for which payment is made under Medicare on a prospectively determined basis.

Geographic area means the area found by HCFA to be the area within which the organization furnishes, or arranges for furnishing, the full range of services that it offers to its Medicare enrollees.

Medicare enrollee means an individual who is entitled to Medicare benefits (Part A and Part B or Part B only) and who has been identified on HCFA records as an enrollee of an eligible organization that has a contract under section 1876 of the Act.

New Medicare enrollee means an individual who—

(a) Enrolls with an organization after the date on which the organization first enters into a risk contract under this subpart;

(b) Is entitled to both Part A and Part B benefits under Medicare or Part B benefits only at the time of the enrollment; and

(c) Was not enrolled with the organization at the time the individual became entitled to benefits under Part A, or eligible to enroll in Part B of Medicare.

New risk contract means a contract entered into under section 1876(g) of the Act (that is, a risk contract under this subpart).

Reasonable cost reimbursement contract means a contract entered into under section 1876(h) of the Act (that is, a cost contract under this subpart).

Urgently needed services means covered services required in order to prevent serious deterioration of an enrollee's health that results from an unforeseen illness or injury if—

(a) The enrollee is temporarily absent from the organization's geographic area; and

(b) Receipt of the health care service cannot be delayed until the enrollee's return to the organization's geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 28573, Aug. 8, 1986]

§ 417.402 Effective date.

Under section 114(c) of Pub. L. 97-248, this subpart was effective on the first day of the first month after the month in which the Secretary certified that the AAPCC methodology, as described in § 417.588, could be implemented. Based on this provision, the effective date of this subpart is February 1, 1985.

ELIGIBILITY AND CONTRACTING REQUIREMENTS AND CONDITIONS

§ 417.404 Introduction.

(a) *General requirements.* In order to participate as an eligible organization under Medicare, an entity must—

(1) Establish that it is an eligible organization; and

(2) Satisfy the contract requirements for an eligible organization to enter into a contract with HCFA.

(b) *Applicable regulations.* (1) Sections 417.406 and 417.407 set forth the requirements an entity must meet to be determined to be an eligible organization. These determinations are made by the Assistant Secretary for Health of the Department.

(2) Sections 417.408 through 417.418 set forth the requirements and conditions that an eligible organization must meet in order to enter into a contract with HCFA. Regulations dealing with the contents of the contract are specified in §§ 417.470 through 417.494.

§ 417.406 Eligible organization determinations.

(a) *Responsibility for making determinations.* (1) HCFA has the responsibility for determining if an entity is an eligible organization.

(2) The application requirements for eligible organizations are set forth in § 110.604 of this title.

(i) Paragraphs (a), (b), (f), (g), and (h) of that section apply to any entity that seeks a determination that it is an eligible organization.

(ii) Paragraphs (c), (d), (e), and (f) of that section apply only to an entity that seeks qualification as an HMO or an HMO.

(3) HCFA uses the procedures set forth in § 110.605 (a) through (d) of this title in determining whether an entity meets the definition of a competitive medical plan as set forth in § 417.407(b). For purposes of this paragraph, references in those sections to "qualified HMO" are deemed references to "competitive medical plan" and references to requirements for qualification are deemed references to the requirements contained in the definition of "competitive medical plan", except that references in those sections to the requirements of section 1301 of the Public Health Service Act, Subpart A of Part 110, and § 110.603 apply only to HMOs and not to CMPs.

(b) *Oversight of continuing eligibility.* (1) HCFA is responsible for overseeing an entity's continuing compliance with the definition of an eligible organization as set forth in § 417.407.

(2) If an entity no longer meets the definition of an eligible organization, HCFA will terminate the entity's contract as specified in § 417.494(b)(iii).

[52 FR 22322, June 11, 1987]

§ 417.407 Definition of an eligible organization.

(a) *State law.* To qualify as an eligible organization, an entity must be organized under the laws of any State and be either an HMO or CMP under paragraph (b) or (c) of this section, respectively.

(b) *Health maintenance organization (HMO).* An HMO is a legal entity that is a qualified HMO as defined in section 1301 of the Public Health Service (PHS) Act. The regulations for qualified HMOs are set forth in Subpart A of Part 110 of this title.

(c) *Competitive medical plan (CMP).* A CMP is a legal entity that meets the following requirements:

(1) Except as specified in paragraph (d) of this section, the entity provides to its enrolled members at least the following services:

(i) Physicians' services performed by physicians.

(ii) Laboratory, X-ray, emergency, and preventive services.

(iii) Out-of-area coverage.

(iv) Inpatient hospital services.

(2) The entity receives compensation (except for deductibles, coinsurance, and copayments) for the health care services it provides to enrolled members on a periodic, prepaid capitation basis regardless of the frequency, extent, or kind of services provided to any member.

(3) The entity provides physicians' services primarily through—

(i) Physicians who are employees or partners of the entity; or

(ii) Physicians or groups of physicians (organized on a group or individual practice basis) under contract with the entity to provide physicians' services.

(4) The entity assumes full financial risk, under the procedures described in § 110.108(b) of this title, on a prospective basis for the provision of health care services listed in paragraph (c)(1) of this section, except that the entity may—

(i) Obtain insurance or make other arrangements for the cost of providing to any enrolled member the health care services listed in paragraph (c)(1) of this section, if the aggregate value of the services exceeds $5,000 in any year;

(ii) Obtain insurance or make other arrangements for the cost of providing health care services listed in paragraph (c)(1) of this section to enrolled members other than through the entity for cases in which medical necessity required that the services be provided before they could be secured through the entity;

(iii) Obtain insurance or make other arrangements for not more than 90 percent of the amount by which the entity's costs for any of its fiscal years exceed 115 percent of its income for that fiscal year; and

(iv) Make arrangements with physicians and other health professionals, health care institutions, or any combination of these to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(5) The entity provides adequately against the risk of insolvency by meeting the fiscal and administrative management requirements of § 110.108(a)(1)(i) through (iv) and (a)(3) of this title.

(d) *Exception for Medicaid prepayment risk contracts.* An entity that had a Medicaid prepayment risk contract before 1970 that did not include provision of inpatient hospital services does not have to meet the requirement of paragraph (c)(1)(iv) of this section.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 22322, June 11, 1987]

§ 417.408 Contract application process.

(a) *Contents of application.* (1) The application for a contract must include supporting information in the form and detail required by HCFA.

(2) Whenever feasible, HCFA will exempt the organization from resubmittal of information it has already submitted to the Assistant Secretary for Health of the Department in connection with a determination made under the provisions of § 417.406.

(b) *Approval of application.* (1) If HCFA approves the application, it will give written notice to the organization, indicating that it meets the requirements for either a risk or reasonable cost contract or only for a reasonable cost contract.

(2) If the organization is dissatisfied with a determination that it meets the requirements only for a reasonable cost contract, it may request reconsideration in accordance with the procedures specified in §§ 417.640 through 417.658.

(c) *Denial of application.* If HCFA denies the application, it will give written notice to the organization indicating—

(1) That it does not meet the contract requirements under section 1876 of the Act;

(2) The reasons why the organization does not meet the contract requirements; and

(3) The organization's right to request reconsideration in accordance with the procedures specified in §§ 417.640 through 417.658.

§ 417.410 Qualifying conditions: General.

(a) In order to qualify for a contract with HCFA under this subpart, an eligible organization must demonstrate its ability to enroll members and to deliver a specified comprehensive range of high quality services efficiently, effectively, and economically to its Medicare enrollees.

(b) An eligible organization must meet qualifying conditions that pertain to operating experience, enrollment, range of services, furnishing of services, and a quality assurance program.

(c) Generally, each qualifying condition is interpreted by a series of standards that are used in surveying an eligible organization to determine its qualifications for a Medicare contract.

(d) Application of the standards enables the surveyor to determine—

(1) The organization's activities;

(2) The extent to which the organization complies with each condition;

(3) The nature and extent of any deficiencies; and

(4) The need for improvement if HCFA should enter into a contract with the organization.

(e) An eligible organization may enter into a risk contract with HCFA if it—

(1) Meets all the applicable requirements in the statute and regulations;

(2) Has at least 5,000 enrollees or 1,500 enrollees if it serves a primarily rural area as defined in § 417.413(b)(3);

(3) Has at least 75 Medicare enrollees or has an acceptable plan to achieve this Medicare membership within 2 years;

(4) Satisfies HCFA that it can bear the potential losses of a risk contract; and

(5) Has not previously terminated or failed to renew a risk contract within the preceding 5 years, unless HCFA determines that circumstances warrant special consideration.

(f) An eligible organization may enter into a reasonable cost contract if it meets one of the following:

(1) The organization qualifies for a risk contract, but chooses a reasonable cost contract.

(2) The organization meets the conditions for entering into a risk contract specified in paragraph (e) of this section except that HCFA does not judge the organization capable of bearing the potential losses of a risk contract.

(g) Regulations on reasonable cost and risk reimbursement are set forth in §§ 417.530 through 417.598.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.412 Qualifying condition: Administration and management.

(a) HCFA will enter into or renew a contract only if it determines that that action would be consistent with the effective and efficient implementation of section 1876 of the Act.

(b) The eligible organization must demonstrate that it—

(1) Has sufficient administrative capability to carry out the requirements of the contract; and

(2) Does not have any agents or management staff or persons with ownership or control interests who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, or social service programs under title XX of the Act.

§ 417.413 Qualifying condition: Operating experience and enrollment.

(a) *Condition.* The organization must demonstrate that it has operating experience and an enrolled population sufficient to provide a reasonable basis for establishing a prospective per capita reimbursement rate or a reasonable cost reimbursement rate, as appropriate.

(b) *Standard: Enrollment and operating experience for organizations to contract on a risk basis:* (1) To be eligible to contract for Medicare reimbursement on a risk basis, a nonrural organization must currently have—

(i) At least 5,000 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to HCFA for achieving a Medicare enrollment of 75 within two years of the beginning of its initial contract period.

(2) To be eligible to contract for Medicare reimbursement on a risk basis, a rural organization must currently have—

(i) At least 1,500 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to HCFA for achieving a Medicare enrollment of 75 within two years of the beginning of its initial contract period.

(3) For purposes of this paragraph, an organization is considered rural if at least 50 percent of its enrollees reside in nonmetropolitan areas. A nonmetropolitan area is an area—

(i) No part of which is within a metropolitan statistical area (MSA) as designated by the Executive Office of Management and Budget; and

(ii) That does not contain a city whose population exceeds 50,000 individuals.

(4) A subdivision or subsidiary of an organization that meets the requirements of paragraph (b)(1) or (b)(2) of this section need not demonstrate that it meets those requirements as an independent unit if the organization assumes responsibility for the financial risk, and adequate management and supervision of health care services furnished by its subdivision or subsidiary.

(c) *Standard: Enrollment and operating experience for organizations to contract on a reasonable cost basis.* To be eligible to contract for Medicare reimbursement on a reasonable cost basis, an organization must currently have an enrolled population sufficient to provide a reasonable basis for entering into a contract.

The organization must have—

(1) At least 1,500 enrollees;

(2) At least 75 Medicare enrollees, or a plan acceptable to HCFA for achieving a Medicare enrollment of 75 within two years of the beginning of its initial contract period; and

(3) At least 250 Medicare enrollees by the beginning of its fourth contract period.

(d) *Standard: Composition of enrollment*—(1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an organization's enrollment may be Medicare and Medicaid beneficiaries.

(2) *Waiver of composition of enrollment standard.* Unless limited by the criteria specified in paragraph (d)(3) of this section, HCFA may waive compliance with the requirements of paragraph (d)(1) of this section if—

(i) The organization is making reasonable efforts to enroll individuals who are not Medicare or Medicaid beneficiaries; and

(ii) Medicare and Medicaid beneficiaries constitute more than 50 percent of the population of the organization's geographic area.

(3) *Limitations on waivers.* HCFA will not grant a waiver that would permit the percentage of Medicare and Medicaid enrollees to exceed the percentage of Medicare and Medicaid beneficiaries in the organization's geographic area.

(e) *Exception to composition of enrollment standard.* An organization that is an existing demonstration project on the date it applies for a contract under the provisions of this subpart and that HCFA finds is making reasonable effort to enroll individuals who are not Medicare or Medicaid beneficiaries is not subject to the composition of enrollment standard specified in paragraph (d)(1) of this section. This exception to the standard applies—

(1) For a period not to exceed three years from the start of the organization's first contract period; or

(2) For a longer period, to be determined by HCFA before the expiration of the three year period, if special circumstances indicate that it is in the best interests of the Medicare program to continue this exception.

(f) *Standard: Open enrollment.* (1) Except as specified in paragraph (f)(2) of this section, an organization must enroll Medicare beneficiaries on a first-come, first-served basis to the limit of its capacity and provide annual open enrollment periods of at least 30 days duration for Medicare beneficiaries.

(2) HCFA may waive the requirement of paragraph (f)(1) of this section if compliance would prevent compliance with the limitation on enrollment of Medicare and Medicaid beneficiaries (paragraph (d) of this section) or result in an enrollment substantially nonrepresentative of the population of the organization's geographic area. The enrollment would be "substantially nonrepresentative" if the proportion of a subgroup to the total enrollment exceeded, by 10 percent or more, its proportion of the population in the organization's geographic area, as shown by census data or other data acceptable to HCFA. For purposes of this paragraph, a subgroup means a class of Medicare enrollees as defined in § 417.582.

§ 417.414 Qualifying condition: Range of services.

(a) *Condition.* The organization must demonstrate that it is capable of delivering to Medicare enrollees the range of services required in accordance with this section.

(b) *Standard: Range of services furnished by eligible organizations*—(1) *Basic requirement.* Except as specified in paragraph (b)(3) of this section, an organization must furnish to its Medicare enrollees (directly or through arrangements with others) all the Medicare services to which those enrollees are entitled that are available to Medicare beneficiaries who reside in the organization's geographic area but are not enrolled in the organization.

(2) *Criteria for availability.* The services are considered available if—

(i) The sources are located within the organization's geographic area; or

(ii) It is common practice to refer patients to sources outside that geographic area.

(3) *Exception for hospice care.* An organization is not required to furnish hospice care as described in Part 418 of this chapter. However, organizations must inform their Medicare enrollees about the availability of hospice care if—

(i) A hospice participating in Medicare is located within the organization's geographic area; or

(ii) It is common practice to refer patients to hospices outside the geographic area.

(4) *Choice of practitioners.* If more than one type of practitioner is qualified to furnish a particular item or service, the organization may select the type of practitioner to be used.

(c) *Standard: Financial responsibility for services furnished outside the organization.* (1) An organization must assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services (as defined in § 417.401) that are obtained by its Medicare enrollees from providers and suppliers outside the organization even in the absence of the organization's prior approval.

(2) An organization must assume financial responsibility for services that the Medicare enrollee attempted to obtain from the organization, but that the organization failed to furnish or unreasonably denied, and that are found, upon appeal by the enrollee under §§ 417.600 through 417.638, to be services that the enrollee was entitled to have furnished to him or her by the organization.

§ 417.416 Qualifying condition: Furnishing of services.

(a) *Condition.* The organization must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The organization must also ensure that the required services, additional services, and any other supplemental services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity.

(b) *Standard: Conformance with conditions of participation, conditions for coverage, and conditions for certification.* (1) Hospitals, SNFs, HHAs, comprehensive outpatient rehabilitation facilities, and providers of outpatient physical therapy or speech pathology services must meet the applicable conditions of participation in Medicare, as set forth elsewhere in this chapter.

(2) Suppliers must meet the conditions for coverage or conditions for certification of their services, as set forth elsewhere in this chapter.

(c) *Standard: Physician supervision.* The organization must provide for supervision by a physician of other health care professionals who are directly involved in the provision of health care as generally authorized under section 1861 of the Act. Except as specified in paragraph (d) of this section, with respect to medical services furnished in an organization's clinic or the office of a physician with whom the organization has a service agreement, the organization must ensure that—

(1) Services furnished by paramedical, ancillary, and other nonphysician personnel are furnished under the direct supervision of a physician;

(2) A physician is present to perform medical (as opposed to administrative) services whenever the clinics or offices are open; and

(3) Each patient is under the care of a physician.

(d) *Exceptions to physician supervision.* The following services may be furnished without the direct personal supervision of a physician:

(1) The organization may permit the services of physician assistants and nurse practitioners (as defined in § 491.2 of this chapter), and the services and supplies incident to their services, to be furnished without the direct personal supervision of a physician. For purposes of this section, the definitions of physician assistants' and nurse practitioners' services and the services and supplies incident to their services for rural health clinics as specified in §§ 405.2414 and 405.2415 of this chapter are applicable.

(2) An organization that contracts on a risk basis may permit the services of clinical psychologists, and the services and supplies incident to their professional services, to be furnished without the direct personal supervision of a physician. For purposes of this section, a clinical psychologist is defined as an individual who—

(i) Holds a doctoral degree in psychology from a program in clinical psychology of an educational institution that is accredited by an organization recognized by the Council on Post-Secondary Accreditation;

(ii) Is licensed or certified at the independent practice level of psychology in the State in which he or she practices; and

(iii) Possesses two years of supervised clinical experience at least one of which is postdegree.

(e) *Standard: Accessibility and continuity.* (1) The organization must ensure that the required services and any other services for which Medicare enrollees have contracted are accessible, with reasonable promptness, to the enrollees with respect to geographic location, hours of operation, and provision of after hours service. Medically necessary emergency services must be available twenty-four hours a day, seven days a week.

(2) The organization must maintain a health (including medical) recordkeeping system through which pertinent information relating to the health care of its Medicare enrollees is accumulated and is readily available to appropriate professionals.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 28573, Aug. 8, 1986]

§ 417.418 Qualifying condition: Quality assurance program.

(a) *Condition.* The organization must make arrangements for a quality assurance program that meets the requirements of this section.

(b) *Standard: Quality assurance program for HMOs.* An HMO must have an ongoing quality assurance program that meets the requirements set forth in § 110.108(h) of this title.

(c) *Standard: Quality assurance program for CMPs.* A CMP must have an ongoing quality assurance program for the health services it furnishes that—

(1) Stresses health outcomes to the extent consistent with the state of the art;

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services;

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed changes; and

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been furnished or services that should have been furnished have not been furnished.

ENROLLMENT, ENTITLEMENT, AND DISENROLLMENT

§ 417.420 Basic rules on enrollment and entitlement.

(a) *Enrollment.* Individuals who are entitled to benefits under both Part A and Part B of Medicare or only Part B may elect to receive those benefits through an organization that has in effect a contract with HCFA under §§ 417.470 through 417.494.

(b) *Entitlement.* If a Medicare beneficiary enrolls with an organization, Medicare will make payments to the organization on his or her behalf for the services to which he or she is entitled, as described in § 417.440.

(c) *Beneficiary liability.* (1) As authorized in § 417.440, the organization may require payment, in the form of premiums or otherwise, from individuals for services not covered under Medicare, as well as deductible and coinsurance amounts attributable to Medicare covered services.

(2) As described in § 417.448, Medicare enrollees of risk organizations are liable for services that they obtain from sources other than the organization, unless the services are—

(i) Emergency or urgently needed; or

(ii) Determined, on appeal under §§ 417.600 through 417.638, to be services that should have been furnished by the organization.

§ 417.422 Eligibility to enroll in an organization.

(a) *General criteria.* Except as specified in § 417.424 and paragraphs (b) and (c) of this section, an organization must enroll, either for an indefinite period or for a specified period of at least 12 months, any individual who—

(1) Is entitled to Medicare benefits under Parts A and B or under Part B only;

(2) Lives within the geographic area served by the organization;

(3) Is not enrolled in any other organization that has entered into a contract under this subpart or Subpart B of this part;

(4) During an enrollment period of the organization, completes and signs the organization's application form and gives whatever information is required for enrollment;

(5) Agrees to abide by the organization's rules after they are disclosed to him or her in connection with the enrollment process;

(6) Is not denied enrollment by the organization under a selection policy, if any, that has been approved by HCFA under § 417.424(b); and

(7) Is not denied enrollment by the organization on the basis of any of the administrative criteria concerning denial of enrollment in § 417.424(a).

(b) *ESRD patients.* Medicare beneficiaries who have been medically determined to have end-stage renal disease are not eligible to enroll in eligible organizations except as specified in § 417.434 concerning reenrollment.

(c) *Hospice patients.* Medicare beneficiaries who have elected hospice care under § 418.24 of this chapter are not eligible to enroll in eligible organizations as long as the hospice election remains in effect.

§ 417.424 Denial of enrollment.

(a) *Basis for denial.* An organization may deny enrollment to an individual who meets the criteria of § 417.422 if acceptance would—

(1) Cause the number of enrollees who are Medicare or Medicaid beneficiaries to exceed 50 percent of the organization's total enrollment;

(2) Prevent the organization from complying with any of the other contract qualifying conditions set forth in §§ 417.412 through 417.418 of this part;

(3) Require the organization to exceed its enrollment capacity; or

(4) Cause the enrollment to become substantially nonrepresentative of the general population in the organization's geographic area.

(b) *Selection policies.* Denial under paragraph (a)(4) of this section must be in accordance with written selection policies approved by HCFA. Enrollment of individuals will not be considered to make the enrollment of the organization substantially nonrepresentative of the general population in the organization's geographic area unless, as a result of the enrollment, the proportion of the subgroup (as defined in § 417.413(f)(2)) of enrollees to which the enrollee belongs as compared to the organization's total enrollment exceeds by at least ten percent its proportion to the general population in the geographic area of the organization.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.426 Open enrollment requirements.

(a) *Basic requirements.* (1) Eligible organizations must provide open enrollment for Medicare beneficiaries for at least 30 consecutive days during each contract year.

(2) During open enrollment, the organization must enroll eligible Medicare beneficiaries in the order in which their applications are received and until its enrollment capacity is reached.

(3) The organization may accept applications from Medicare beneficiaries after it has reached capacity if it places those individuals on a waiting list and enrolls them in chronological order as vacancies occur.

(b) *Capacity to accept new enrollees.* (1) If an organization chooses to limit enrollments because of its capacity, it must notify HCFA at least 90 days before the beginning of its open enrollment period and, at that time, provide HCFA with its reasons for limiting enrollment.

(2) HCFA will evaluate the organization's submittal under paragraph (b)(1) of this section.

(3) The organization must promptly notify HCFA if there is any change in its enrollment capacity.

(c) *Reserved vacancies.* An organization may set aside a reasonable number of vacancies for an anticipated new group contract or for anticipated new members of an existing group contract that will have its enrollment period after the Medicare open enrollment period during the contract year—

(1) Subject to HCFA's approval; and

(2) On condition that any vacancies set aside that are not filled within a reasonable period of time after the beginning of the group contract enrollment period be made available to Medicare beneficiaries and other nongroup applicants under the requirements of this subpart.

§ 417.428 Marketing activities.

(a) *Required marketing activities.* An organization must meet the following requirements.

(1) Offer its plan to Medicare beneficiaries and provide to those interested in enrolling, adequate written descriptions of the organization's rules, procedures, benefits, fees and other charges, services, and other information necessary for beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period (whether time limited or continuous) in an appropriate manner through appropriate media, throughout its enrollment area.

(3) Submit all marketing materials to HCFA at least 45 days before their planned distribution.

(b) *Prohibited marketing activities—general.* In offering its plan to Medicare beneficiaries, an organization may not engage in any of the following practices or activities:

(1) Practices that are discriminatory. For example, the organization may not engage in any activity intended to recruit Medicare beneficiaries from higher income areas (usually an indicator of better health) without making a comparable effort to enroll Medicare beneficiaries from lower income areas.

(2) Activities that could mislead or confuse Medicare beneficiaries, or misrepresent the organization, its marketing representatives, or HCFA. For example, the organization may not claim that it is recommended or endorsed by HCFA or that HCFA recommends that the beneficiary enroll in the organization. It may, however, explain that the entity is approved as an organization for purposes of participation in Medicare.

(3) Offers of gifts or payment as an inducement to enroll in the organization. This does not prohibit the explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the organization, such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance or preventive services.

(4) Door-to-door solicitation of Medicare beneficiaries.

(5) Distribution of marketing materials if, before the expiration of the 45-day period described in paragraph (a)(3) of this section, the organization receives written notice from HCFA that HCFA has disapproved the material because it is inaccurate or misleading or it misrepresents the organization, its marketing representatives or HCFA.

(c) *Marketing activities of risk organizations.* In addition to the generally permitted or prohibited marketing activities described in paragraphs (a) and (b) of this section, a risk organization must provide potential Medicare enrollees with adequate written descriptions of the additional benefits or services, or reductions in premiums, deductible or copayments that may pertain under risk reimbursement.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 8901, Mar. 20, 1987]

§ 417.430 Application procedures.

(a) *Application forms.* (1) The application form must comply with HCFA instructions regarding format and content and must include the beneficiary's signature and authorization for disclosure and exchange of necessary information between HCFA and the organization.

(2) The organization must file and retain application forms for the period specified in HCFA instructions.

(b) *Handling of applications.* An organization must have an effective system for receiving, controlling, and processing applications from Medicare beneficiaries. The system must meet the following conditions and requirements:

(1) Each application is dated as of the day it is received.

(2) Applications are processed in chronological order by date of receipt.

(3) The organization notifies the beneficiary in writing of acceptance or denial of the application promptly.

(4) The notice of acceptance—

(i) Specifies the date on which the organization will request HCFA to make the enrollment effective; or

(ii) If the organization is currently enrolled to capacity, explains the procedures that will be followed when vacancies occur.

(5) The notice of denial explains the reason for denial.

(6) The organization transmits the information necessary for HCFA to add the beneficiary to its records of the organization's Medicare enrollees—

(i) Within 30 days from the date of application or from the date a vacancy occurs for an applicant who was accepted while the organization was enrolled to capacity; or

(ii) Within an additional period of time approved by HCFA on a showing by the organization that it needs more time.

(7) The organization promptly notifies the beneficiary of the effective month of his or her enrollment as a Medicare enrollee, when it receives that information from HCFA.

(8) If the organization accepts applications while it is enrolled to capacity, its procedures ensure that vacancies are filled in chronological order by date of application of beneficiaries who are still eligible to enroll, unless that would result in failure to comply with any of the qualifying conditions set forth in § 417.413.

§ 417.432 Conversion of enrollment.

(a) *Basic rule.* An organization must accept as a Medicare enrollee any individual who is enrolled in the organization for the month immediately before the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(b) *Effective date of conversion.* Unless the individual chooses to disenroll from the organization, the individual's conversion to a Medicare enrollee is effective the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(c) *Prohibition against disenrollment.* An organization may not disenroll an individual who is converting under the provisions of paragraph (a) of this section unless one of the conditions specified in § 417.460 is met.

(d) *Application form.* The individual who is converting must sign an application form as described in § 417.430(a).

(e) *Expedite submittal of information to HCFA.* The organization must notify HCFA, within the following time frames, of the enrollee's authorization for disclosure and exchange of information and the information necessary for HCFA to include the enrollee in its records as a Medicare enrollee of the organization:

(1) At least 30, but no earlier than 90, days before the enrollee—

(i) Attains age 65; or

(ii) Reaches his or her 25th month of entitlement to social security disability benefits under title II of the Act or railroad retirement disability benefits under section 7(d) of the Railroad Retirement Act of 1974.

(2) Within 30 days after the enrollee initiates a course of renal dialysis, or on or before the day he or she enters a hospital in anticipation of a kidney transplant.

(f) *Two-for-one rule concerning conversion of current nonrisk Medicare enrollees.* A risk organization that is receiving reimbursement for current nonrisk Medicare enrollees on a reasonable cost basis may, as provided in § 417.444, convert those enrollees to its risk reimbursement membership if it enrolls two new Medicare enrollees for each current nonrisk enrollee it converts under § 417.446. Selection of the current nonrisk Medicare enrollees to be converted must be unbiased as described in § 417.446(c).

§ 417.434 Reenrollment.

If an organization requires periodic reenrollment, it must reenroll Medicare enrollees unless there is a basis for disenrollment as set forth in § 417.460.

§ 417.436 Membership rules for enrollees.

(a) *Maintaining rules.* An organization must maintain written membership rules that deal with, but need not be limited to—

(1) Procedures for paying premiums and other charges for which Medicare enrollees may be liable;

(2) Grievance and appeal procedures;

(3) Disenrollment rights;

(4) The obligation of an enrollee who is permanently moving out of the organization's geographic area; that is, expects to be absent from the area for more than 90 days, must notify the organization of the move or absence;

(5) How and where to obtain services from or through the organization; and

(6) Any other matters that HCFA may prescribe.

(b) *Availability of rules.* The organization must furnish a copy of the rules to each Medicare enrollee.

(c) *Changes in rules.* If an organization changes its rules, it must notify its Medicare enrollees of the changes at least 30 days before the effective date of the changes.

§ 417.440 Entitlement to health care services from an organization.

(a) *Basic rules.* (1) Subject to the conditions and limitations set forth in this subpart, a Medicare enrollee of an organization is entitled to receive health care services and supplies directly from, or through arrangements made by, the organization as specified in this section and §§ 417.442–417.446.

(2) A Medicare enrollee is also entitled to receive timely and reasonable payment directly (or have payment made on his or her behalf) for services he or she obtained from a provider or supplier outside the organization if those services are—

(i) Emergency services or urgently needed services as defined § 417.401;

(ii) Services denied by the organization and found (upon appeal under §§ 417.600 through 417.638) to be services the enrollee was entitled to have furnished by the organization.

(b) *Scope of services*—(1) *Part A and Part B services.* Except as specified in paragraphs (c), (d) and (e) of this section, a Medicare enrollee is entitled to receive from the organization all the services and supplies that are covered by Part A and Part B of Medicare (if he or she is entitled to benefits under both programs) or by Medicare Part B (if he or she is entitled only under that program) that are available to individuals residing in the geographical area served by the organization.

(2) *Supplemental services elected by enrollee.* A Medicare enrollee of an organization may elect to pay for optional services that are offered by the organization in addition to the covered Part A and Part B services, and, for risk organizations, in addition to the additional benefits required under § 417.442. The organization may not set health status standards for those enrollees whom it will accept for these optional supplemental services.

(3) *Supplemental services imposed by risk reimbursement organizations.* Subject to the approval of HCFA, a risk organization may require Medicare enrollees to accept and pay for services in addition to the covered Part A and Part B services. These services must be imposed on all applicable enrollees without regard to health status. HCFA will approve the supplemental services if it determines that the requirement will not discourage enrollment in the organization by other Medicare beneficiaries.

(4) *Additional benefits from risk organizations required by statute.* Subject to the conditions stated in § 417.442, a new Medicare enrollee or a

current nonrisk Medicare enrollee who converts to risk reimbursement under § 417.444 is eligible to receive, in addition to the covered Part A and Part B benefits for which he or she is eligible, benefits consisting of one or both of the following:

(i) A reduction in the organization's premium rate or in other charges for services furnished to Medicare enrollees.

(ii) Provision of health benefits or services and supplies beyond the required Part A and Part B coverage.

(5) *Special supplemental benefits.* Under conditions described in § 417.444(c), current nonrisk Medicare enrollees who are not converted to the risk portion of the contract, may enroll in a special supplemental plan, if offered by the organization, for some or all of the additional benefits described in paragraph (b)(4) of this section.

(c) *Limitation on hospice care*—(1) *Extent of the limitation.* If a Medicare enrollee elects to receive hospice care under the provisions of § 418.24 of this chapter, the enrollee waives his or her right to receive from the organization any Medicare services, including services equivalent to hospice care, that are related to the treatment of the terminal condition for which hospice care was elected or to a related condition, except for services furnished by the individual's attending physician, if that physician is an employee or contractor of the organization and is not an employee of the designated hospice or receiving compensation from the hospice for those services.

(2) *Effective date of limitation.* The limitation in paragraph (c)(1) of this section begins on the effective date of the beneficiary's election of hospice care under § 418.24 of this chapter and remains in effect until the earlier of—

(i) The effective date of the enrollee's revocation of the election of hospice care as described in § 418.28 of this chapter; or

(ii) The date the enrollee exhausts his or her hospice benefits.

(3) *Payment to organization.* For the period that the Medicare enrollee's election of hospice care is in effect, payment will be made to reasonable cost organizations only as described in § 417.531 and to risk organizations only as described in § 417.585.

(d) *Limitation on provision of inpatient hospital services.* If a beneficiary's effective date of coverage, as defined by § 417.450 of this part, in an organization with a risk contract occurs during an inpatient stay in a hospital paid for under Part 412 of this chapter, the organization—

(1) Is not responsible for the provision of any of the inpatient hospital services under Part A during the stay and is not required to pay for those services;

(2) Must assume responsibility for payment for or provision of inpatient hospital services under Part A on the day after the day of discharge from the inpatient stay; and

(3) Is responsible for the full scope of services under paragraph (b) of this section, other than inpatient hospital services under Part A, beginning on the effective date of enrollment.

(e) *Extension of provision of inpatient hospital services.* If an enrollee's effective date of disenrollment, as defined by § 417.460 of this part, occurs during an inpatient stay in a hospital paid for under Part 412 of this chapter and the stay is provided or arranged for by the organization, or the organization is financially responsible for the hospitalization under paragraph (a)(2) of this section, the organization—

(1) Is financially responsible for payment of the inpatient services under Part A through the date the beneficiary is discharged from the inpatient stay; and

(2) Is not responsible for the provision of services, furnished on or after the effective date of disenrollment, other than inpatient hospital services under Part A.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987]

§ 417.442 Risk organizations: Conditions for provision of additional benefits.

(a) *General rule.* Except as provided in paragraph (b) of this section, an organization with a risk contract must provide its Medicare enrollees with the additional benefits described in

§ 417.440(b)(4) during a contract period if, prior to the contract period, the organization's ACRs (calculated separately for Part A and Part B enrollees and Part B-only enr ollees) are less than the average of the per capita rates of payment for those beneficiaries that HCFA will be making to the organization. The computation of the value of the additional benefits, the ACR, and the average of the per capita payment rates are described in §§ 417.590 through 417.594.

(b) *Exceptions*—(1) *Reduced payment election.* An organization is not obligated to furnish additional services under paragraph (a) of this section if it has requested a reduction in its monthly payment from HCFA under § 417.592(e), and it—

(i) Elects to receive reduced payment so that there is no difference between the average of its per capita rates of payment and its ACR; or

(ii) Elects to receive partially reduced payment and furnish Medicare enrollees with additional benefits described in § 417.440 (b)(4) so that the combined value of benefits and reduced payment is equivalent to the difference between the average of its per capita rates of payment and its ACR.

(2) *Benefit stabilization fund.* An organization may elect to have a part of the value of the additional benefits it must provide under paragraph (a) of this section withheld in a benefit stabilization fund as described in § 417.596.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.444 Special rules for current nonrisk Medicare enrollees of an organization under a risk contract.

(a) *Condition for additional benefits.* Current nonrisk Medicare enrollees of a risk organization may retain that status indefinitely and, therefore, are not entitled to the additional benefits under § 417.442 unless HCFA determines that the enrollee's status must be changed or a change is requested by the enrollee, as follows:

(1) HCFA determines that, for administrative reasons or because there are fewer than 75 current nonrisk Medicare enrollees remaining in the organization, all current nonrisk Medicare enrollees of an organization must be covered under the risk provisions of the contract; and

(i) HCFA notifies each affected enrollee of the decision at least 90 days prior to the effective date;

(ii) The current nonrisk Medicare enrollees complete and sign forms stating that they understand and accept the new rules and benefits that will be applicable to them; and

(iii) The organization notifies each affected enrollee, in writing, at least 30 days in advance, of the date upon which his or her coverage under the risk portion of the contract takes effect.

(2) A current nonrisk Medicare enrollee requests, using the same or a similar form to that described in paragraph (a)(1)(ii) of this section, that he or she be covered under the risk portion of the contract, and—

(i) The organization has enrolled two new Medicare enrollees for each of these current nonrisk Medicare enrollees; and

(ii) In cases where there are more current nonrisk Medicare enrollees than can be accommodated due to the two-for-one rule, the selection of those to be covered under the risk portion of the contract is made in an unbiased manner, as provided in § 417.446(c).

(b) *Conditions for special supplemental benefits.* A current nonrisk Medicare enrollee of an organization with a risk contract who is precluded from enrollment under the risk portion of the contract because of the two-for-one rule in § 417.446(a) may enroll in a plan for special supplemental benefits, if one is offered by the organization. The plan may cover some or all of the additional benefits described in § 417.440(b)(4). The plan must—

(1) Be offered to all current nonrisk Medicare enrollees of the organization who meet the requirements of this paragraph;

(2) Be offered at no cost to those enrollees;

(3) Offer a uniform package of benefits to all those enrollees;

(4) Be voluntary for those enrollees;

(5) Not affect the selection of the enrollees who will be converted to cov-

erage under the risk portion of the contract;

(6) Restrict the enrollees who accept the plan from receiving payment directly or on their behalf for covered items and services received from sources outside the organization, in the same manner and subject to the conditions described in § 417.420(c);

(7) Provide that reimbursement for the special supplemental services for such enrollees be made from the savings the organization achieves, in the manner described in § 417.442; and

(8) Be offered with full disclosure of all provisions, especially the restriction described in paragraph (b)(6) of this section.

(c) *Notification.* Current nonrisk Medicare enrollees must be informed of the availability of any special supplemental benefits at least 90 days prior to the beginning of the organization's enrollment period, or other opportunity to enroll.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.446 Two-for-one enrollment criteria.

(a) *Basic rule.* In order to receive reimbursement on a risk basis for a current nonrisk Medicare enrollee, a risk organization must enroll two new Medicare enrollees for each current nonrisk Medicare enrollee who is converting. Selection of those enrollees to be converted must be made in an unbiased manner as prescribed in paragraphs (b) and (c) of this section.

(b) *Procedure for conversion.* (1) The organization must keep an accurate count of new Medicare enrollees and, on request by HCFA, be able to demonstrate that it has done so.

(2) Unused opportunities to convert current nonrisk Medicare enrollees to the risk provisions of the contract may be carried forward indefinitely from one contract period to another regardless of the death or subsequent disenrollment of a new Medicare enrollee.

(3) The organization may convert current nonrisk Medicare enrollees continuously as vacancies occur under the two-for-one criteria or during a special period designated for this purpose at least annually.

(i) The organization need not have a special period if no conversions are possible.

(ii) If special periods are held, current nonrisk Medicare enrollees must be informed about the period 60 days before it begins.

(iii) If waiting lists are used, the organization may convert the current nonrisk Medicare enrollees as vacancies occur, or on a group basis (for example, 10 or 20 at a time) for administrative ease. In either case, the enrollees must be converted in the order in which they appear on the waiting list. Placement on a waiting list must be on an equitable basis such as first-come, first-served.

(iv) The organization may allow continuous application for conversion with applicants being placed on a waiting list and converted as vacancies occur.

(c) *Requirements for unbiased conversion.* The organization, whether it uses a waiting list, a special period or another approach such as selection by lottery, must convert current nonrisk Medicare enrollees to the risk provisions of the contract in an unbiased manner. This means that the organization must—

(1) Inform in a timely, open, and complete manner all current nonrisk Medicare enrollees of their right to convert to the risk portion of the contract and the procedures for doing so;

(2) Not discriminate among the current nonrisk Medicare enrollees on the basis of geographic location, health status, or whether or not they have enrolled in the organization's plan for special supplemental benefits, if one is offered;

(3) Not discriminate among current nonrisk Medicare enrollees who are in similar circumstances, such as length of previous enrollment; and

(4) If it uses a waiting list, place the current nonrisk Medicare enrollees on the list in an equitable manner, such as first-come, first-served during a special period, a lottery, or greatest length of time enrolled in the organization.

§ 417.448 Restriction on payments for services received by Medicare enrollees of risk organizations.

(a) *Basic rule.* Except for emergency and urgently needed services as defined in § 417.401, risk organizations are not required to make payments to or on behalf of certain Medicare enrollees, for any services received by the enrollees that are not provided—

(1) Directly by the organization; or

(2) Through arrangements made by the organization.

(b) *Application.* The restriction on payments for services imposed by paragraph (a) of this section applies to services received by—

(1) New Medicare enrollees;

(2) Current nonrisk Medicare enrollees who convert to risk reimbursement; and

(3) Current nonrisk Medicare enrollees who elect special supplemental benefit plans.

(c) *End of restriction.* The restriction on payments imposed by paragraph (a) of this section ends when a Medicare enrollee—

(1) Is disenrolled; or

(2) Permanently leaves the geographic area serviced by the risk organization and the organization and enrollee make arrangements for membership to continue as provided in § 417.460(a)(2)(iv).

(d) *Timing.* The effective dates for the end of the restriction on payments, as discussed in paragraph (c) of this section, are as follows:

(1) *Disenrollment.* As of the first day of the month in which termination of enrollment is effective, as provided in § 417.460(b)(3).

(2) *Permanent move.* As of the first day of the first month following the month in which the enrollee notifies the organization, as required in § 417.436(a)(4), that he or she has permanently moved out of the geographic area served by the risk organization.

[51 FR 28573, Aug. 8, 1986]

§ 417.450 Effective date of coverage.

(a) *Basic rules.* Except as specified in paragraph (b) of this section, and notwithstanding the provisions of § 417.440(d).

(1) Medicare's liability for payments to an organization on behalf of a Medicare beneficiary begins on the first day of the month in which he or she is—

(i) Entitled to Medicare benefits; and

(ii) Enrolled in an organization; and

(2) The effective month of coverage may not be earlier than the first month after, nor later than the third month after the month in which HCFA receives the information necessary to include the beneficiary as a Medicare enrollee of the organization in HCFA records.

(b) *Exceptions.* (1) HCFA may approve a later month if it is requested by the organization and the beneficiary.

(2) If an individual becomes an organization enrollee before becoming entitled to Medicare Part B benefits, the effective month of coverage is the first month for which he or she becomes entitled to Medicare Part B benefits.

(c) *Notice of effective date of coverage.* HCFA will promptly advise the organization of the month for which HCFA's liability for payment begins for each beneficiary added to its records as an enrollee of the organization.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 8901, Mar. 20, 1987]

§ 417.452 Liability of Medicare enrollees.

(a) *Deductibles and coinsurance.* (1) A Medicare enrollee of an organization is responsible for applicable Medicare deductible and coinsurance amounts, unless the organization's charges for these amounts are reduced under § 417.442.

(2) The deductible and coinsurance amounts may be paid by the enrollee or on his or her behalf by another individual, organization, or entity. The payments may be made in the form of a premium, membership fee, charge per unit or similar charge.

(3) The sum of the amounts the organization charges its Medicare enrollees for Medicare deductibles and coinsurance may not exceed, on the average, the actuarial value of the deductible and coinsurance the Medicare enrollees otherwise would have been liable for had they not enrolled in the

organization or in another organization.

(b) *Services not covered under Medicare.* Unless the services are provided under § 417.442 or § 417.444(b), a Medicare enrollee of an organization is liable for payment for—

(1) All services that are not covered under Medicare Part A or Part B; or

(2) If entitled only to Medicare Part B benefits, all services that are not covered under Medicare Part B.

(c) *Services for which Medicare is not primary payor.* A Medicare enrollee of an organization is liable for payments made to the enrollee for all covered services for which Medicare is not the primary payor as provided in § 417.528.

(d) *Optional supplemental benefits plan.* (1) The organization may offer its Medicare enrollees a supplemental benefit plan to cover deductible and coinsurance amounts, or services not covered under Medicare, or both.

(2) If a supplemental benefit plan premium includes charges for both noncovered services and the deductible and coinsurance amounts applicable to covered services, the portion of the premium that is for deductibles and coinsurance must be computed separately and must be disclosed to the beneficiary during the enrollment process and before he or she elects coverage options.

(3) The sum of the amounts an organization charges its Medicare enrollees for services that are not covered under Part A or Part B may not exceed the ACR for these services.

(e) *Coverage of Part A services for Part B-only Medicare enrollees.* If an organization furnishes coverage of Medicare Part A services to a Medicare enrollee entitled to Part B only, the organization's premium (or other payment method) for these services may not exceed the ACR for these services. In addition, if a risk organization furnishes these services and supplemental services, which are the same as the additional benefits furnished Medicare enrollees of the organization who are entitled to benefits under both Parts A and B, the organization's combined premium for both these groups of services that the Part B [illegible] must pay may not ex[illegible] weighted average AAPCC for Part A services (or the Medicare payment for Part A services, if it is less) for the Medicare enrollees in the organization.

§ 417.454 Charges to Medicare enrollees.

(a) The organization must agree to charge its Medicare enrollees only for the—

(1) Deductible and coinsurance amounts applicable to furnished covered services;

(2) Charges for noncovered services or services for which the enrollee is liable as described in § 417.452; and

(3) Services for which Medicare is not the primary payor as provided in § 417.528.

(b) A risk organization must report, within 90 days after the end of the contract period, all premiums, enrollment fees, and other charges collected from its Medicare enrollees during that period.

§ 417.456 Refunds to Medicare enrollees.

(a) *Definitions.* As used in this section—

Amounts incorrectly collected means amounts collected that are in excess of those specified in § 417.452. It includes amounts collected when the enrollee was believed not entitled to Medicare benefits if the enrollee is later determined to have been entitled to Medicare benefits and Medicare is liable for payments as specified in § 417.450.

Other amounts due means amounts due a Medicare enrollee for services obtained outside the organization if they were—

(1) Emergency services;

(2) Urgently needed services for which the organization has assumed financial responsibility; or

(3) On appeal under §§ 417.600 through 417.638, found to be services the enrollee was entitled to have furnished by the organization.

(b) *Basic commitment.* An organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and any other amounts due the enrollees or others on their behalf.

(c) *Refund by lump sum payment.* An organization must make refunds to its current and former Medicare enrollees, or to others who have made payments on behalf of enrollees, by lump sum payment for the following:

(1) Incorrectly collected amounts that were not collected as premiums.

(2) Other amounts due.

(3) All amounts due, if the organization is going out of business.

(d) *Refund by premium adjustment or lump sum payment or both.* An organization may make refund by adjustment of future premiums, by lump sum payment, or by a combination of both methods, for amounts that were incorrectly collected in the form of premiums or through a combination of premium payments and other charges.

(e) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort by the organization, the organization must make the refund in accordance with State law.

(f) *Reduction by HCFA.* If the organization does not make refund in accordance with paragraphs (b) through (d) of this section by the end of the contract period following the contract period during which an amount was determined to be due an enrollee, HCFA will reduce its payment to the organization by the amounts incorrectly collected or otherwise due, and arrange for those amounts to be paid to the Medicare enrollee.

§ 417.458 Recoupment of uncollected deductible and coinsurance amounts.

An organization agrees to recoup deductible and coinsurance amounts for which Medicare enrollees were liable in a previous contract period only in the following circumstances:

(a) The organization failed to collect the deductible and coinsurance amounts during the contract period in which they were due because of—

(1) Underestimation of the actuarial value of the deductible and coinsurance amounts; or

(2) A billing error.

(b) The organization has identified the amounts and obtained advance HCFA approval of the recoupment and the method and timing of recoupment.

(c) The organization collects these amounts no later than the end of the contract period following the contract period during which they were found to be due.

§ 417.460 Disenrollment of beneficiaries and termination of payments to an organization.

(a) *Disenrollment of health insurance program beneficiaries.* An organization may not, orally or in writing, or by any action or inaction, request or encourage a Medicare enrollee to disenroll, except in the following circumstances:

(1) *Failure to pay premiums*—(i) *Basic rules.* Except as specified in paragraph (a)(1)(iii) of this section, an organization may disenroll a Medicare enrollee who fails to pay premiums or other charges imposed by the organization for deductible and coinsurance amounts for which the enrollee is liable, if the organization—

(A) Can demonstrate to HCFA that it made reasonable efforts to collect the unpaid amount;

(B) Gives the enrollee written notice of disenrollment, including an explanation of the enrollee's right to a hearing under the organization's grievance procedures; and

(C) Sends the notice of disenrollment to the enrollee before it notifies HCFA.

(ii) *When HCFA's liability ends.* (A) HCFA's liability to make monthly capitation payments to the organization on behalf of the enrollee ends as of the first day of the month following the month in which termination of enrollment as a Medicare enrollee is effective, as shown on HCFA records.

(B) Disenrollment will be effective no earlier than the month immediately after, and no later than the third month after, the month in which the disenrollment notice is received in acceptable form by HCFA.

(iii) *Exception.* If a Medicare enrollee of an organization fails to pay the separate premium (or the corresponding portion of a single premium) for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept) but pays the premium for the deductible and coinsurance amounts, the organization may discontinue the optional supplemental benefits but may not disenroll the enrollee.

(2) *Enrollee moves out of the organization's geographic area*—(i) *Basic rule.* Except as provided in paragraph (a)(2)(iv) of this section, an organization must disenroll a Medicare enrollee who moves out of its geographic area and does not voluntarily disenroll under paragraph (b) of this section if the organization—

(A) Establishes, on the basis of a written statement from the enrollee or other evidence acceptable to HCFA, that the enrollee has permanently moved out of its geographic area; and

(B) Complies with the notice requirements set forth in paragraph (a)(1)(i) of this section.

(ii) *Failure to disenroll does not expand geographic area.* If the organization does not disenroll an enrollee who has moved out of its geographic area, that area is not automatically expanded to encompass the location of the enrollee's new residence.

(iii) *When HCFA's liability ends.* The provisions of paragraph (a)(1)(ii) of this section apply.

(iv) *Exception.* An organization may retain a Medicare enrollee who permanently moves out of the organization's geographic area as a member, if the enrollee agrees. For purposes of this exception, the following provisions apply:

(A) A permanent move means an uninterrupted absence of more than 90 days from the organization's geographic area.

(B) The organization and the enrollee may mutually agree upon restrictions for obtaining services while the enrollee resides out of the organization's geographic area. However, restrictions may not be imposed on the scope of services described in § 417.440.

(C) If the enrollee returns to the organization's geographic area, the restrictions under § 417.448(a) prohibiting Medicare payment for services not provided or arranged for by the organization apply again immediately.

(D) Organizations that choose to exercise this exception must make the option available to all Medicare enrollees who permanently move out of the organization's geographic area. (However, organizations that are affiliated with other organizations may limit this option to enrollees who move to the geographic area served by the other organizations.)

(3) *Failure to convert to risk provisions of contract*—(i) *Disenrollment and notice.* A risk organization must disenroll a current nonrisk Medicare enrollee if the enrollee refuses to convert to the risk provisions of the organization's contract after HCFA has determined under § 417.444(a)(1) that all of the organization's current nonrisk Medicare enrollees must be converted. The organization must notify the enrollee that failure to convert will result in disenrollment. The notice must be sent at least 30 days before the organization notifies HCFA of the disenrollment.

(ii) *When HCFA's liability ends.* The provisions of paragraph (a)(1)(ii) of this section apply.

(4) *Enrollee commits fraud or permits abuse of organization membership card.* (i) A Medicare beneficiary may be disenrolled by the organization if the beneficiary knowingly provides, on the application form, fraudulent information upon which an organization relies and which materially affects his or her eligibility to enroll in the organization, or if the beneficiary intentionally permits others to use his or her membership card to receive services from the organization.

(ii) In either case, the organization must give the beneficiary a written notice of termination of enrollment. The notice must be mailed to the enrollee prior to the submission of the disenrollment notice to HCFA. The notice must include an explanation of the enrollee's right to have the disenrollment heard under the grievance procedures established under § 417.436.

(iii) The liability of HCFA to make monthly capitation payments to the organization on behalf of the beneficiary terminates as of the first day of the month in which the termination of the membership in the organization is made effective, as shown on HCFA records. In no event may that month be earlier than the month immediately following, or later than the third month following, the month in which the disenrollment notice is received in acceptable form by HCFA.

(iv) The organization must report any disenrollment made under the provisions of this paragraph (a)(4) to the Inspector General of the Department.

(5) *Enrollee's entitlement to benefits under the supplementary medical insurance program ends.* (i) The liability of HCFA to make monthly capitation payments to the organization on behalf of the beneficiary ends with the month immediately following the last month of entitlement to benefits under Part B of Medicare. The beneficiary may be continued as an enrollee other than as a Medicare enrollee by the organization under its regular plan if the organization and the enrollee so choose.

(ii) If an enrollee loses entitlement to benefits under Part A of Medicare but remains entitled to benefits under Part B, the enrollee automatically continues as a Medicare enrollee of the organization and is entitled to receive and have payment made for Part B services beginning with the month immediately following the last month of his or her entitlement of Part A benefits.

(6) *Disenrollment for cause*—(i) *When cause may be cited.* An organization may disenroll a Medicare enrollee for cause if the enrollee's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his or her continuing membership in the organization seriously impairs the organization's ability to furnish services to either the enrollee or other members.

(ii) *Effort to resolve the problem.* The organization must make a serious effort to resolve the problem presented by the enrollee, including the use (or attempted use) of internal grievance procedures.

(iii) *Consideration of extenuating circumstances.* The organization must ascertain that the enrollee's behavior is not related to the use of medical services or mental illness.

(iv) *Documentation.* The organization must document the problems, efforts, and medical conditions as described in paragraphs (a)(6) (i), (ii), and (iii) of this section.

(v) *HCFA review of an organization's proposed disenrollment.* HCFA will decide, based on a review of the documentation submitted by the organization, whether disenrollment requirements have been met. HCFA will make this decision within 20 working days of receipt of the documentation material, and notify the organization within five working days after its decision is made.

(vi) *Effective date of disenrollment.* If HCFA permits an organization to disenroll an enrollee for cause, the disenrollment takes effect on the first day of the calendar month after the month in which the organization complies with the notice requirements in paragraphs (a)(1)(i) (B) and (C) of this section (other than the right to a hearing as described in paragraph (a)(1)(i)(B) of this section).

(vii) *When HCFA's liability ends.* The provisions of paragraph (a)(1)(ii)(A) of this section apply.

(7) *Death of the enrollee.* The liability of HCFA for payments to the organization on behalf of a Medicare enrollee who dies ends as of the first day of the month following the month of death.

(b) *Disenrollment by the enrollee.* (1) A Medicare enrollee may disenroll at any time by giving the organization a signed, dated request in the form and manner prescribed by the organization. The enrollee may request a certain disenrollment date but it may be no earlier than the first day of the month following the month in which the organization receives the request. The organization must submit a disenrollment notice to HCFA promptly.

(2) An organization must provide the enrollee with a copy of the written request for termination of enrollment. Risk organizations must also provide a written statement explaining that the enrollee remains enrolled in the organization until the effective date of the disenrollment and is subject to the requirements described in § 417.448(a) until that date.

(3) HCFA's responsibility for payments to the organization ends with the close of the month of termination requested by the enrollee.

(4) If the organization fails to submit the correct and complete

notice required in paragraph (b)(1) of this section on a timely basis, the organization must reimburse HCFA for any capitation payments received after the month in which payments would have ceased if the requirement has been met timely.

(c) *Effect of termination or default of contract*—(1) *Termination of contract.* If the contract between HCFA and the organization is terminated by mutual consent or by unilateral action of either party, HCFA's liability for payments ends as of the first day of the month after the last month for which the contract is in effect.

(2) *Default of contract.* If the organization defaults on the contract before the end of the contract year because of bankruptcy or other reasons, HCFA will—

(i) Determine the month in which its liability for payments ends; and

(ii) Notify the organization and all affected Medicare enrollees as soon as practicable.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 28574, Aug. 8, 1986; 52 FR 8901, Mar. 20, 1987]

CONTRACT REQUIREMENTS

§ 417.470 Basis and scope.

(a) *Basis.* Sections 417.472 through 417.494 implement those portions of section 1876(c), (g), (h), and (i) of the Act that pertain to the contract between HCFA and an organization for participation in the Medicare program.

(b) *Scope.* Sections 417.472 through 417.494 set forth—

(1) Specific contract requirements; and

(2) Procedures for renewal, nonrenewal, or termination of a contract.

§ 417.472 Basic contract requirements.

(a) *Submittal of contract.* In order for an eligible organization to participate in the Medicare program, an authorized official of the organization must sign and submit a contract that meets the requirements of this subpart and any other provisions required by HCFA.

(b) *Contract provisions for all eligible organizations.* The contract must provide that the organization agrees to comply with all the applicable requirements and conditions set forth in this subpart and general instructions of HCFA.

(c) *Other contract provisions.* In addition to the requirements set forth in §§ 417.474 through 417.488, the contract must contain any other terms and conditions that HCFA requires to implement section 1876 of the Act.

(d) *Exemption from Federal procurement regulations.* The Federal Acquisition Regulations and HHS Acquisition Regulations contained in Title 48 of the Code of Federal Regulations do not apply to Medicare contracts under section 1876 of the Act.

(e) *Compliance with civil rights laws.* The organization must comply with title VI of the Civil Rights Act of 1964 (regulations at 45 CFR Part 80), section 504 of the Rehabilitation Act of 1973 (regulations at 45 CFR Part 84), and the Age Discrimination Act of 1975 (regulations at 45 CFR Part 91).

(f) *Authority to waive conflicting contract requirements.* Under section 1876(i)(5) of the Act, the Secretary is authorized to administer the terms of this subpart without regard to provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if he or she determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.474 Effective date and term of contract.

(a) The contract must specify its effective date.

(b) The effective date may not be earlier than the date it is signed by both HCFA and the organization.

(c) The contract must specify the duration of its term. However, the initial term of the contract must be at least 12 months, but no more than 23 months; and any subsequent term must be for a period of 12 months.

§ 417.476 Waived conditions.

The contract must specify the following information for each of the qualifying conditions required under §§ 417.410 through 417.418 that is waived by HCFA:

(a) The specific terms of the waiver.

(b) The expiration date of the waiver.

(c) Any other information required by HCFA.

§ 417.478 Requirements of other laws and regulations.

The contract must provide that the organization agrees to comply with—

(a) The requirements for PRO review of services furnished to Medicare enrollees as set forth in Subchapter D of this chapter;

(b) Sections 1318(a) and (c) of the PHS Act, which pertain to disclosure of certain financial information;

(c) Section 1301(c)(8) of the PHS Act, which relates to liability arrangements to protect members of the organization; and

(d) The reporting requirements in § 110.108(j)(1) of this title, which pertain to the monitoring of an organization's continued compliance. For purposes of this paragraph, references in that section to "HMO"are also deemed references to "CMP".

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.480 Maintenance of records: Reasonable cost organizations.

A contract with a reasonable cost organization must provide that the organization agrees to maintain books, records, documents, and other evidence of accounting procedures and practices that—

(a) Are sufficient to—

(1) Ensure an audit trail; and

(2) Properly reflect all direct and indirect costs claimed to have been incurred under the contract; and

(b) Include at least records of the following:

(1) Ownership, organization, and operation of the organization's financial, medical, and other recordkeeping systems.

(2) Financial statements for the current contract period and three prior periods.

(3) Federal income tax or information returns for the current contract period and three prior periods.

(4) Asset acquisition, lease, sale, or other action.

(5) Agreements, contracts, and subcontracts.

(6) Franchise, marketing, and management agreements.

(7) Schedules of charges for the organization's fee-for-service patients.

(8) Matters pertaining to costs of operations.

(9) Amounts of income received by source and payment.

(10) Cash flow statements.

(11) Any financial reports filed with other Federal programs or State authorities.

§ 417.481 Maintenance of records: Risk organizations.

A contract with a risk organization must provide that the organization agrees to maintain, and make available to HCFA upon request, books, records, documents, and other evidence of accounting procedures and practices that—

(a) Are sufficient to—

(1) Establish component rates of the ACR for determining additional and supplementary benefits; and

(2) Determine the rates utilized in setting premiums for State insurance agency purposes; and

(b) Include at least any records or financial reports filed with other Federal agencies or State authorities.

§ 417.482 Access to facilities and records.

The contract must provide that the organization agrees to the following:

(a) HHS may evaluate, through inspection or other means, the quality, appropriateness, and timeliness of services furnished under the contract to its Medicare enrollees.

(b) HHS may evaluate, through inspection or other means, the facilities of the organization when there is reasonable evidence of some need for that inspection.

(c) HHS, the Comptroller General, or their designees may audit or inspect any books and records of the organization or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract.

(d) HHS may evaluate, through inspection or other means, the enrollment and disenrollment records for the current contract period and three prior periods, when there is reasonable evidence of some need for that inspection.

(e) In the case of a reasonable cost organization, to make available for the purposes specified in paragraphs (a), (b), (c), and (d) of this section, its premises, physical facilities, and equipment, its records relating to its Medicare enrollees, the records specified in § 417.480 and any additional relevant information that HCFA may require.

(f) That the right to inspect, evaluate, and audit, will extend through three years from the date of the final settlement for any contract period unless—

(1) HCFA determines there is a special need to retain a particular record or group of records for a longer period and notifies the organization at least 30 days before the normal disposition date;

(2) There has been a termination, dispute, fraud, or similar fault by the organization, in which case the retention may be extended to three years from the date of any resulting final settlement; or

(3) HCFA determines that there is a reasonable possibility of fraud, in which case it may reopen a final settlement at any time.

§ 417.484 Requirement applicable to related entities.

(a) *Definition.* As used in this section, "related entity" means any entity that is related to the organization by common ownership or control and—

(1) Performs some of the organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the organization at a cost of more than $2,500 during a contract period.

(b) *Requirement.* The contract must provide that the organization agrees to require all related entities to agree that—

(1) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent books, documents, papers, and records of the subcontractor involving transactions related to the subcontract; and

(2) The right under paragraph (b)(1) of this section to information for any particular contract period will exist for a period equivalent to that specified in § 417.482(f).

§ 417.486 Disclosure of information and confidentiality.

The contract must provide that the organization agrees—

(a) To submit to HCFA—

(1) All financial information required under §§ 417.530 through 417.576 and for final settlement; and

(2) Any other information necessary for the administration or evaluation of the Medicare program.

(b) To comply with the requirements set forth in Part 420, Subpart C, of this chapter pertaining to the disclosure of ownership and control information;

(c) To comply with the requirements of the Privacy Act, as implemented by 45 CFR Part 5b and Subpart B of Part 401 of this chapter, with respect to any system of records developed in performing carrier or intermediary functions under §§ 417.532 and 417.533; and

(d) To meet the confidentiality requirements of § 405.1026(a) of this chapter for medical records and for all other information on enrollees, not covered under paragraph (c) of this section, that is contained in its records or obtained from HCFA or others.

§ 417.488 Written notice of termination.

A risk contract must provide that if the contract is terminated, the organization agrees to give to its Medicare enrollees, and to be responsible for the cost of, the following notices.

(a) A written notice of the termination at least 60 days before the termination date.

(b) A written description of alternatives available for obtaining Medicare services after termination.

§ 417.490 Renewal of contract.

A contract with an organization is renewed automatically for the next 12-month period unless HCFA or the organization decides not to renew, in accordance with § 417.492.

§ 417.492 Nonrenewal of contract.

(a) *Nonrenewal by the organization.* (1) If an organization does not intend to renew its contract, it must—

(i) Give written notice to HCFA at least 90 days before the end of the current contract period;

(ii) Notify each Medicare enrollee by mail at least 60 days before the end of the contract period; and

(iii) Notify the general public at least 30 days before the end of the contract period, by publishing a notice in one or more newspapers of general circulation in each community or county located in the organization's geographic area.

(2) HCFA may accept a nonrenewal notice submitted less than 90 days before the end of a contract period if—

(i) The organization notifies its Medicare enrollees and the public in accordance with paragraph (a)(1) of this section; and

(ii) Acceptance would not otherwise jeopardize the effective and efficient administration of the Medicare program.

(b) *Nonrenewal by HCFA.* If HCFA decides not to renew a contract, it will notify interested parties of certain information, as follows:

(1) The organization at least 90 days before the end of the contract period;

(2) The organization's Medicare enrollees at least 60 days before the end of the contract period;

(3) The general public at least 30 days before the end of the contract period; and

(4) The organization that if the organization is dissatisfied with the decision, and HCFA's decision was based on one of the reasons specified in § 417.640(c), the organization may appeal that decision in accordance with procedures specified in §§ 417.640 through 417.682.

§ 417.494 Modification or termination of contract.

(a) *Modification or termination by mutual consent.* (1) HCFA and an organization may modify or terminate a contract at any time by written mutual consent.

(2) If the contract is modified, the organization must notify its Medicare enrollees of any changes that HCFA determines are appropriate for notification.

(3) If the contract is terminated, the organization must notify its Medicare enrollees, and HCFA will notify the general public, at least 30 days before the termination date.

(b) *Termination by HCFA.* (1) HCFA may terminate a contract for any of the following reasons:

(i) The organization has failed substantially to carry out the terms of the contract.

(ii) The organization is carrying out the contract in a manner that is inconsistent with the effective and efficient implementation of section 1876 of the Act.

(iii) HCFA determines that the organization no longer meets the applicable conditions necessary to qualify as an eligible organization under section 1876 of the Act and this subpart.

(2) If HCFA determines that a contract will be terminated, it will send written notice to the organization and indicate the organization's right to appeal that determination in accordance with the procedures specified in §§ 417.640 through 417.682.

(3) An organization with a risk contract must notify its Medicare enrollees of the termination as described in § 417.488.

(4) HCFA will notify the organization's Medicare enrollees and the general public of the termination at least 30 days before the termination date.

(c) *Termination by the organization.* The organization may terminate the contract if HCFA has failed substantially to carry out the terms of the contract.

(1) The organization must notify HCFA at least 90 days before the effective date of the termination and must include in its notice the reasons for the termination.

(2) The organization must notify its Medicare enrollees of the termination at least 60 days before the termination date. Risk organizations must also provide a written description of alternatives available for obtaining Medicare services after termination of the contract. The organization is responsible for the cost of these notices.

(3) The organization must notify the general public of the termination at least 30 days before the termination date.

(4) The contract will be terminated effective 60 days after the notice to Medicare enrollees is mailed, as required in paragraph (c)(2) of this section.

(5) HCFA's liability for payment ends as specified in § 417.460(c).

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 22322, June 11, 1987]

Change of Ownership and Leasing of Facilities

§ 417.520 General provisions.

(a) *Definitions.* As used in this subpart—

Lessee means the entity to which an organization leases all or part of its facilities.

Lessor means the organization that leases all or part of its facilities to another entity.

Novation agreement means a document executed and signed by the current owner of the organization, the proposed new owner, and HCFA, under which HCFA recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(b) *Basic rules*—(1) *Change of ownership.* Except as provided in paragraph (b)(3)(ii) of this section, a change of ownership of an organization makes its Medicare contract invalid with respect to the period following the change of ownership, unless there is a novation agreement.

(2) *Effect of change without novation agreement.* If the new owner wishes to participate in the Medicare program, it must notify HCFA of the change of ownership and apply for and enter into a contract in accordance with §§ 417.472 through 417.488.

(3) *Advance notice of HCFA.* (i) An organization with a contract under this subpart that is considering or negotiating a change of ownership must notify HCFA at least 60 days before the anticipated change.

(ii) If the organization fails to provide the required notice to HCFA timely, it will continue to be liable for capitation payments HCFA makes to it on behalf of Medicare enrollees after the date of change of ownership.

§ 417.521 What constitutes change of ownership.

(a) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(b) *Unincorporated sole proprietorship.* Transfer of title and property to another party constitutes change of ownership.

(c) *Corporation.* (1) The merger of the organization's corporation into another corporation or the consolidation of the organization with one or more other corporations, resulting in a new corporate body, constitutes a change of ownership.

(2) Transfer of corporate stock or the merger of another corporation into the organization's corporation, with the organization surviving, does not ordinarily constitute change of ownership.

§ 417.522 Novation agreement requirements.

(a) *Conditions for HCFA approval of a novation agreement.* HFCA will approve a novation agreement if the following conditions are met:

(1) *Advance notification.* The organization notifies HCFA at least 60 days before the date of the proposed change of ownership.

(2) *Advance submittal of agreement.* The organization submits to HCFA, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section and one copy of other relevant documents required by HCFA.

(3) *HCFA's determination.* HCFA determines that—

(i) The proposed new owner is in fact a successor in interest to the contract;

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program; and

(iii) The Assistant Secretary of Health has certified that the successor organization meets the PHS requirements to qualify as an eligible organization.

(b) *Provisions of a novation agreement*—(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.*

(i) The previous owner must guarantee performance of the contract by the new owner during the contract period; or

(ii) The new owner must post a performance bond that is satisfactory to HCFA.

(4) *Records Access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to HCFA to permit an accurate determination of costs for the final settlement of the contract period.

§ 417.523 Effect of leasing of an organization's facilities.

(a) *Effect of lessee status.* If an organization leases all or part of its facilities to another entity, the lessee does not acquire eligible organization status under section 1876 of the Act.

(b) *Effect of lease of all facilities.* (1) If an organization leases all of its facilities to another entity, the contract terminates.

(2) If the lessee wishes to participate in Medicare as an eligible organization, it must apply for and enter into a contract in accordance with this subpart.

(c) *Effect of partial lease of facilities.* If the organization leases part of its facilities to another entity, its contract with HCFA remains in effect while HCFA surveys the organization to determine whether it continues to be in compliance with the requirements and qualifying conditions specified in §§ 417.410 through 417.418.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

General Reimbursement Rules

§ 417.524 Payment to eligible organizations: General.

(a) *Basic rule.* The payments made to an eligible organization in accordance with the provisions of this subpart for furnishing covered Medicare services are in lieu of any payment that would otherwise be made to a beneficiary or the organization under sections 1814(b) and 1833(a) of the Act.

(b) *Basis of payment.* Reimbursement to eligible organizations is made on either a reasonable cost basis or a risk basis depending on the type of contract the organization has with HCFA. In certain cases, organizations that have contracted on a risk basis also receive reimbursement on a reasonable cost basis for certain Medicare enrollees. (See § 417.444 for a discussion of this provision.)

§ 417.526 Payment for covered services.

Sections 417.530 through 417.576 set forth the principles that HCFA follows in determining Medicare reimbursement to an eligible organization that has a reasonable cost contract. Sections 417.580 through 417.598 describe the per capita method of Medicare reimbursement to eligible organizations that contract on a risk basis.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.528 Payment for covered services—Medicare not primary payor.

(a) HCFA may not reimburse an organization for services to the extent that Medicare is not the primary payor under the provisions of section 1862(b) of the Act. The circumstances under which an organization may charge, or authorize a provider to charge, for covered Medicare services where Medicare is not the primary payor are stated in paragraphs (b) and (c) of this section.

(b) If a Medicare enrollee receives otherwise covered services from an eligible organization for which the enrollee is entitled to benefits under a State or Federal worker's compensation law or plan, an automobile medical, or no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the organization may charge, or authorize a provider that furnished the service to charge—

(1) The insurance carrier, employer, or other entity that is liable to pay for these services; or

(2) The Medicare enrollee, to the extent that he or she has been compensated under the law or policy.

(c) An eligible organization may charge an employer group health plan for covered services furnished by the organization to a Medicare enrollee and may charge the Medicare enrollee to the extent that he or she has been reimbursed by the employer group health plan for these covered services if—

(1) The Medicare enrollee is covered by the group health plan; and

(2) HCFA is not permitted to make payment for the covered services furnished under the provisions of sections 1862(b)(2) or 1862(b)(3)(A)(i) of the Act.

(d) An organization must—

(1) Identify payors that are primary to Medicare under section 1862(b) of the Act;

(2) Determine the amounts payable by these payors; and

(3) Coordinate the benefits of its Medicare enrollees with these payors.

REASONABLE COST REIMBURSEMENT

§ 417.530 Basis and scope.

Sections 417.530 through 417.576 set forth the principles that HCFA follows in determining the amount it will pay to an organization for services furnished by the organization to its Medicare enrollees for whom HCFA reimburses the organization on a reasonable cost basis (or under section 1886 of the Act, as applicable). These principles are based on sections 1861(v) and 1876 of the Act and are, for the most part, the same as those set forth in Parts 412 and 413 of this chapter for reimbursement of provider costs on a reasonable cost basis.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34832, Sept. 30, 1986]

§ 417.531 Hospice care services.

(a) If a Medicare enrollee of an organization with a reasonable cost contract makes an election under § 418.24 of this chapter to receive hospice care services, reimbursement for these services is made to the hospice participating in the Medicare program that furnishes the services in accordance with Part 418 of this chapter.

(b) While the enrollee's hospice election is in effect, the organization may be reimbursed on a reasonable cost basis for only the following covered Medicare services furnished to the Medicare enrollee:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the organization and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which hospice care was elected or a condition related to the terminal condition.

§ 417.532 General considerations.

(a) *Conditions and criteria for reimbursement.* (1) The costs incurred by the organization to furnish services covered by Medicare are reimbursable if they are—

(i) Proper and necessary;

(ii) Reasonable in amount; and

(iii) Except as provided in § 417.550, appropriately apportioned among the organization's Medicare enrollees, other enrollees, and nonenrolled patients.

(2) In determining fair and equitable reimbursement for the organizations, HCFA generally applies the cost reimbursement principles set forth in § 413.5 of this chapter.

(3) Except as specified in paragraph (a)(4) of this section, in judging whether costs are reasonable, HCFA applies the weighted average of the AAPCCs of each class of the organization's Medicare enrollees (as defined in § 417.582) for the organization's ge-

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ographic area as an absolute limitation on the total amount payable.

(4) For contract periods beginning before January 1, 1986, an entity with an existing cost contract is not subject to the reimbursement limitation specified in paragraph (a)(3) of this section. In judging whether costs for these organizations are reasonable, HCFA may consider the per capital costs incurred by the organization for its Medicare enrollees in relation to the AAPCC for the organization's geographic area or a similar area. In those cases, HCFA will use the AAPCC as a general guideline for reimbursement to a reasonable cost organization rather than as a reimbursement limitation.

(b) *Method and amount of reimbursement to the organization.* (1) HCFA makes interim per capita payments each month for each Medicare enrollee, equivalent to the interim per capita cost rate determined in accordance with § 417.570.

(2) HCFA adjusts the interim per capita rate as necessary during the contract period and makes final adjustments at the end of the contract period.

(3) In determining the amount due the organization, HCFA deducts from the reasonable cost actually incurred by the organization for covered services furnished to its Medicare enrollees, an amount equal to the actuarial value of the applicable Medicare Part A and Part B deductible and coinsurance amounts that would have applied to the covered services for which payment is being made if these enrollees had not enrolled in the organization or another eligible organization.

(c) *Election by organization.* An organization must elect, on an individual provider basis, one of the following methods for reimbursement for hospital and SNF services it furnishes to Medicare enrollees:

(1) Direct payment by HCFA.

(2) Direct payment by the organization.

(d) *Notice of election.* The election must be made in writing before the beginning of the contract period and is binding for that period.

(e) *Reimbursement by organization.* If the organization elects to pay providers directly, as provided in paragraph (c) of this section, it must—

(1) Determine the eligibility of its Medicare enrollees to receive covered services through the organization;

(2) Make proper coverage decisions and appropriate payments, in accordance with §§ 421.100 and 421.200 of this chapter, for the services furnished to its Medicare enrollees;

(3) Ensure that providers maintain and furnish appropriate documentation of physician certification and recertification, to the extent required under Subpart B of Part 424 of this chapter; and

(4) Carry out any other procedures required by HCFA.

(f) *Review of organization's bill processing capabilities.* If the organization elects to pay providers directly, HCFA will determine whether the organization has the experience and capability to carry out the responsibilities specified in paragraph (e) of this section in an efficient and effective manner.

(g) *Direct reimbursement by HCFA.* Under the election specified in paragraph (c)(1) of this section, HCFA pays a provider for the covered services it furnishes to the organization's Medicare enrollees on a reasonable cost basis or on the basis of prospectively determined rates, whichever is applicable to that provider as described in Parts 412 and 413 of this chapter. HCFA will deduct these payments and any other payments made by intermediaries or carriers on behalf of the organization (for example, payments for emergency or urgently needed services made under § 417.558(a)) in computing the payments to the organization under paragraph (b) of this section.

(h) *Reimbursement for services furnished to Medicare beneficiaries not enrolled in the organization.* HCFA reimburses the organization for services it furnishes to Medicare beneficiaries who are not its enrollees through the organization's Medicare intermediary or carrier, as appropriate.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 53 FR 6648, Mar. 2, 1988]

§ 417.533 Part B carrier responsibilities.

In paying for Part B services furnished to its enrollees by suppliers, the organization is responsible for—

(a) Determining the eligibility of individuals to receive those services through the organization;

(b) Making proper coverage decisions and appropriate payment as authorized under § 421.200 of this chapter for the services for which its Medicare enrollees are eligible; and

(c) Carrying out any other procedures that HCFA may require.

§ 417.534 Allowable costs.

(a) *Definition—Allowable costs* means the direct and indirect costs, including normal standby costs incurred by the organization, that are proper and necessary for efficient delivery of needed health care services. They include the costs of furnishing services to the organization's Medicare enrollees, other enrollees, and nonenrolled patients, which are typical "provider" costs, and costs (such as marketing, enrollment, membership, and operation of the organization) that are peculiar to health care prepayment organizations.

(b) *Basic rules.* (1) The allowability of an organization's costs for furnishing services is generally determined in accordance with principles applicable to provider costs, as set forth in § 417.536.

(2) The allowability of other costs is determined in accordance with principles set forth in §§ 417.538 through 417.550.

(3) Costs for covered services for which Medicare is not the primary payor, as described in § 417.528, are not allowable.

§ 417.536 Provider cost reimbursement principles applicable to the organizations.

(a) *Applicability.* Unless otherwise specified in this subpart, the principles or reasonable cost reimbursement set forth in Parts 412 and 413 of this chapter are applicable to the organization's costs when incurred by an organization or by providers of services and other facilities owned or operated by the organization, or related to the organization by common ownership or control. The most common examples of these costs are set forth in this section.

(b) *Depreciation.* An appropriate allowance for depreciation on buildings and equipment is an allowable cost, in accordance with §§ 413.134, 413.144, and 413.149 of this chapter.

(c) *Interest expense.* Necessary and proper interest on both current and capital indebtedness is an allowable cost, in accordance with § 413.153 of this chapter.

(d) *Cost of educational activities.* An appropriate part of the net cost of approved educational activities of a provider or other health care facility owned or operated by an organization is an allowable cost in accordance with § 413.85 of this chapter.

(e) *Compensation of owners.* An appropriate amount of compensation for services of owners is an allowable cost, if the services are actually performed and are necessary, as specified in § 413.102 of this chapter.

(f) *Bad debts.* (1) In accordance with § 413.80 of this chapter, bad debts are deductions from revenue and may be included as allowable costs only if—

(i) They are attributable to Medicare deductible and coinsurance amounts for which the Medicare enrollee is liable; and

(ii) The organization has made a reasonable, but unsuccessful, effort to collect those amounts.

(2) If all or part of the deductible and coinsurance amounts is payable through a monthly premium or other periodic payment, the amount allowed as a bad debt may not exceed three times the monthly rate for the actuarial value of the deductible and coinsurance amounts, or its equivalent, if the periodic payment is on other than a monthly basis.

(3) Any bad debt related to a service furnished to a Medicare enrollee or the organization, and claimed on a cost report submitted for reimbursement by a provider or other facility reimbursed on a cost basis, may not be claimed as a bad debt by the organization.

(g) *Charity and courtesy allowances.* As specified in § 405.420 of this chapter, charity and courtesy allowances are deductions for revenue and may not be included as allowable costs.

(h) *Research costs.* As specified in § 413.90 of this chapter, costs incurred for research purposes, over and above patient care, are not allowable costs.

(i) *Value of services of nonpaid workers.* The value of services of nonpaid workers of an organization is not an allowable cost, except as provided in § 413.94 of this chapter.

(j) *Purchase discounts and allowances and refund of expenses.* Discounts and allowances that an organization receives on purchases of goods and services and refunds of previous expense payments must be deducted from the costs to which they relate, in accordance with § 413.98 of this chapter.

(k) *Cost to related organizations.* (1) The costs of services, facilities, or supplies furnished to an organization by a related entity are allowable at the cost to the related entity in accordance with § 413.17 of this chapter.

(2) An entity is not considered related to the organization merely because—

(i) It has a risk or incentive agreement under which the organization reimburses or compensates the entity for services it furnishes to the organizations's enrollees; or

(ii) Substantially all the services the entity furnishes are furnished to the organization's enrollees.

(3) However, an entity described in paragraph (k)(2) of this section and an organization are considered related if either of them is in a position to exercise significant management or ownership influence or control over the other.

(l) *Return on equity capital of proprietary providers owned by the organization.* An allowance for a reasonable return on equity capital invested and used in providing services is allowable in addition to the reasonable cost of services furnished by a proprietary provider owned by the organization. The amount of the allowance is determined in accordance with § 413.157 of this chapter.

(m) *Limitations on reimbursement.* Medicare payment for covered services furnished by entities owned by or operated by, or related to, an organization reimbursed on a reasonable cost basis is subject to certain provisions of Subpart E of Part 405, and Parts 412 and 413 of this chapter that pertain to reasonable cost and reasonable charge. Those provisions include, but are not necessarily limited to, the following:

(1) For ESRD treatment, the limitations authorized under §§ 405.542, 405.544, and 413.170 of this chapter.

(2) For services of physical, occupational, and speech therapists and other therapists and nonphysician health specialists, the limitations set forth in § 413.106 of this chapter.

(3) For drugs, the allowable cost as determined under § 413.110 of this chapter.

(4) The overall cost limits established in accordance with § 413.30 of this chapter.

(5) The limitation to the lesser of reasonable cost or customary charges, as set forth in § 413.13 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986]

§ 417.538 Enrollment and marketing costs.

(a) *Principle.* Enrollment and marketing costs incurred by an organization in the course of performing the activities described in §§ 417.426 through 417.436 are allowable as provided in this section.

(b) *Definition.* Allowable enrollment and marketing costs are those necessary and proper costs incurred in offering the organization's plan to potential enrollees in accordance with this part. Those costs include selling, advertising, promotional, and other marketing costs and may not exceed an amount that would be incurred by a prudent and cost-conscious management.

(c) *Application.* Enrollment and marketing costs are allowable, whether incurred directly by organization staff or under contract with marketing specialists or other outside consultants.

(d) *Reimbursement limitation.* The relatively higher costs that an organization is likely to incur in initially offering its plan to Medicare beneficiaries are taken into account in determining whether enrollment and marketing costs are reasonable in amount. However, if such costs exceed amounts that would be paid by prudent management, the excess is not allowable.

§ 417.540 Membership costs.

(a) *Principle.* Membership costs are allowable if incurred in maintaining and servicing subscriber contracts for prepayment enrollees.

(b) *Kind of costs included.* Membership costs include, but are not limited to, reasonable costs incurred in connection with maintaining statistical, financial, and other data on enrollees.

§ 417.542 Reinsurance costs.

Reinsurance costs are not allowable.

§ 417.544 Physicians' services furnished directly by the organization.

(a) *Principles.* Conpensation paid by an organization to physicians is an allowable cost to the extent that it is commensurate with the compensation paid for similar services performed by similar physicians practicing in the same or a similar locality. Physician compensation may take various forms, but the aggregate compensation allowable must be reasonable in relation to the services personally furnished. If aggregate physician compensation costs exceed what is normally incurred, the excess is not a reasonable cost.

(b) *Application.* In determining the allowability of the costs of physicians' services, the cost of personal services (for example, expenses attributable to salaries, wages, incentive payments, fringe benefits) must be distinguished from the cost of nonpersonal services (for example, expenses attributable to facilities, equipment, support personnel, supplies). To be allowable, compensation must be reasonable in relation to the personal services furnished.

§ 417.546 Physicians' services and other Part B supplier services furnished under arrangements.

(a) *General principle.* Except as specified in paragraph (b) of this section, the amount paid by an organization for physicians' services and other Part B supplier services furnished under arrangements is an allowable cost to the extent it is reasonable. Costs are considered reasonable if they—

(1) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(2) Are comparable to costs incurred for similar services furnished by similar physicians or other suppliers in the same or a similar geographic area.

(b) *Special limitation for entities with existing cost contracts.* For entities with existing cost contracts, the provisions of this paragraph apply for contract periods beginning before January 1, 1986.

(1) If the organization pays for physicians' services and other Part B supplier services on other than a fee-for-service basis—

(i) Except as specified in paragraph (b)(1)(ii) of this section, the costs incurred by the organization may be considered reasonable if they—

(A) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(B) Are comparable to costs incurred for similar services furnished by similar physicians or other suppliers in the same or a similar locality.

(ii)(A) If a physician group to whom the organization makes payment compensates its physicians on a fee-for-service basis, the organization's payment to the group may not exceed the reasonable charges for those services, as defined in Subpart E of Part 405 of this chapter.

(B) Payment in excess of the limits specified in paragraph (b)(1)(ii)(A) of this section is allowable if the group has procedures under which members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In such cases, the amount paid by the organization is considered reasonable if it meets the conditions specified in paragraph (b)(1)(i) of this section.

(2) If the organization pays for physicians' services and other Part B supplier services on a fee-for-service basis—

(i) Except as specified in paragraph (b)(2)(ii) of this section, the costs incurred by the organization are considered reasonable if they do not exceed—

(A) The reasonable charges for those services, as defined in Subpart E of Part 405 of this chapter; and

(B) The amount that HCFA would pay for those services, if they were furnished to beneficiaries who are not enrolled in the organization and who receive the services from sources other than providers of services or other entities that are reimbursed on a reasonable cost basis.

(ii) Payment to a physician group organized on an individual-practice basis is not subject to the limitations specified in paragraph (b)(2)(i) of this section if the group pays its physicians on a fee-for-service basis and has procedures under which the members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In such cases, the amount paid by the organization is considered reasonable if it meets the conditions specified in paragraph (b)(1)(i) of this section.

EDITORIAL NOTE: Section 417.546 as added at 50 FR 1346, Jan. 10, 1985, contains information collection requirements which will not be effective until approval has been obtained from the Office of Management and Budget. A notice will be published in the FEDERAL REGISTER.

§ 417.548 Provider services through arrangements.

(a) *Principle.* The cost incurred by an organization for covered services furnished under arrangement with a provider is allowable to the extent that it would be allowable and reimbursable under Parts 412 and 413 of this chapter, unless, upon the organization's petition to HCFA, the organization can demonstrate to HFCA's satisfaction that payment in excess of the amount authorized under Parts 412 and 413 of this chapter is justified on the basis of advantages gained by the organization.

(b) *Application.* An advantage gained must represent a real and tangible benefit received by the organization for the excess cost incurred, and any excess payment is subject to other applicable requirements of Parts 405, 412 and 413 of this chapter, including tests of reasonableness. For example, in the case of an arrangement an organization has with a provider that is located outside the organization's geographic area and that is not related to the organization by common ownership or control, payment of the provider's charges to the organization (rather than the provider's reasonable cost as determined under Parts 412 and 413 of this chapter) may be justified in exchange for the advantages of not having to incur the administrative costs of determining the provider's reasonable cost and of making a more timely final settlement with the organization. However, repayment of the provider's charges would be acceptable only if—

(1) The provider furnishes services to the organization's enrollees infrequently;

(2) The charges represent an insignificant portion of total Medicare reimbursement to the organization; and

(3) The charges do not exceed the customary charges by the provider to its other patients for similar services.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34832, Sept. 30, 1986]

§ 417.550 Special Medicare program requirements.

(a) *Principle.* Except as specified in paragraph (d) of this section, Medicare reimburses the total reasonable cost incurred by an organization for activities specified in this section that are solely for Medicare purposes and unique to Medicare contracts under section 1876 of the Act.

(b) *Application.* The following costs are reimbursed in full for cost-reimbursed Medicare enrollees:

(1) The reasonable cost of reporting data concerning increases and decreases in Medicare enrollment.

(2) The reasonable cost incurred, solely for Medicare purposes, for the independent certification of the organization's cost report required under § 417.576.

(3) The total reasonable cost of special data that HCFA requires from organizations solely for program planning and evaluation purposes.

(c) *Prior approval.* Costs that are reimbursed in full under this section must be separately budgeted and approved by HCFA before the contract period begins.

(d) *Exception: Apportioned costs.* (1) Payment in full is limited to the costs specified in paragraph (b) of this section.

(2) The normal administrative costs incurred by the organization in obtaining Medicare reimbursement (such as the cost of maintaining and reporting membership, statistical, and actuarial data needed to determine the amount of reimbursement to the organization, and the cost of preparing costs reports) must be apportioned in accordance with § 417.552.

§ 417.552 Cost apportionment: General provisions.

(a) *Basic rule.* Except as provided in § 417.556(c), the organization must apportion its total allowable direct and indirect costs among its Medicare enrollees, its other enrollees, and its nonenrolled patients—

(1) In accordance with §§ 417.530 through 417.576; and

(2) Using methods approved by HCFA.

(b) *Purpose of apportionment.* The purpose of apportionment is to ensure that—

(1) The cost of services furnished to Medicare enrollees is not borne by other enrollees and nonenrolled patients; and

(2) The cost of the services furnished to other enrollees and nonenrolled patients is not borne by Medicare.

§ 417.554 Apportionment: Provider services furnished directly by the organization.

The Medicare share of the cost of covered services furnished to Medicare enrollees by providers that are owned or operated by the organization or are related to the organization by common ownership or control must be determined in accordance with the apportionment methods set forth in § 405.480, Part 412 of this chapter, and §§ 413.55 and 413.24 of this chapter.

[51 FR 28574, Aug. 8, 1986, as amended at 51 FR 34832, Sept. 30, 1986]

§ 417.556 Apportionment: Provider services furnished by the organization through arrangements with others.

The Medicare share of the cost of covered services furnished to Medicare enrollees through arrangements with providers other than those specified in § 417.554 must be determined as follows:

(a) The Medicare share must be based on the cost the organization pays the provider under their arrangement, to the extent that cost is reasonable and within the limits established by §§ 417.534 through 417.548.

(b) Except as specified in paragraph (c) of this section, apportionment must be on the same approved basis that is used by the provider for Medicare beneficiaries who are not Medicare enrollees of the organization, subject to the conditions and limitations set forth in § 417.548.

(c) If, because of the special nature or terms of the organization's arrangement with the provider, apportionment on the basis specified in paragraph (b) of this section would result in Medicare's bearing the costs of furnishing services to individuals other than the organization's Medicare enrollees, apportionment must be on another basis that is approved by HCFA and that will ensure that Medicare does not pay any of the cost of furnishing services to individuals who are not Medicare enrollees of the organization.

(d) If the organization elects to have providers reimbursed by the organization's Medicare intermediary, the Medicare share is the amount the intermediary paid the provider.

§ 417.558 Emergency and urgently needed services, and out-of-area services for which the organization assumes financial responsibility: Sources of payment.

(a) *Payment by intermediary.* An intermediary may reimburse its providers for the reasonable cost of covered emergency or urgently needed services as defined in § 417.401, and other covered out-of-area services for which the organization assumes financial responsibility.

(b) *Payment by organization*—(1) *Basic rule.* Except as specified in paragraph (b)(2) of this section, a payment by the organization to a provider for emergency or urgently needed services as defined in § 417.401 or other out-of-area services is allowable only to the extent it would be allowable under Parts 412 and 413 of this chapter.

(2) *Exception.* Payment in excess of the reasonable cost allowed under Parts 412 and 413 of this chapter is allowable only if the organization demonstrates to HCFA's satisfaction that it is justified on the basis of advantages gained by the organization, as set forth in § 417.548.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34832, Sept. 30, 1986]

§ 417.560 Apportionment: Part B physician and supplier services.

(a) *Medical services furnished directly by the organization.* The total allowable cost of Part B physician and supplier services furnished by employees or partners of the organization or by a related entity of the organization must be apportioned on the basis of the ratio of covered Part B services furnished to Medicare enrollees to total services furnished to all the organization's enrollees and nonenrolled patients. The organization must use a method for reporting costs that is approved by HCFA. HCFA will base its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(b) *Medical services furnished under arrangements made by the organization.* When the organization pays for Part B physician and supplier services on some basis other than fee-for-service, the reasonable cost the organization pays under its financial arrangement with the physician or supplier must be apportioned between Medicare enrollees and others based on the ratio of covered services furnished to Medicare enrollees to the total services furnished to all enrollees and nonenrolled patients. If apportionment on this basis would result in Medicare bearing the cost of furnishing services to individuals who are not Medicare enrollees, the Medicare share must be determined on another basis (approved by HCFA) to ensure that Medicare pays only for services furnished to Medicare enrollees.

(c) *Medical services furnished under an arrangement that provides for the organization to pay on a fee-for-service basis.* The Medicare share of the cost of Part B physician and supplier services furnished to Medicare enrollees under arrangements, and paid for by the organization on a fee-for-service basis, is determined by multiplying the total amount for all such services by the ratio of charges for covered services furnished to Medicare enrollees to the total charges for all such services.

(d) *Emergency services, urgently needed services, and other covered medical services for which the organization assumes financial responsibility.* (1) Except as provided in paragraph (d)(2) of this section, the Medicare share of the cost of Part B emergency or urgently needed services or other Part B services that are not furnished by a provider and for which the organization accepts financial responsibility is determined in accordance with paragraphs (b) and (c) of this section.

(2) For contract periods beginning before January 1, 1986, in the case of entities with existing cost contracts, payment of the physician's or supplier's charges instead of the reasonable charges as defined in Subpart E of Part 405 of this chapter may be justified if the organization demonstrates to HCFA's satisfaction that—

(i) The physician or supplier furnishes services infrequently to enrollees of the organization;

(ii) The charges represent an insignificant portion of total Medicare payments to the organization; and

(iii) The charges do not exceed the amounts the physician or supplier charges other patients for similar services.

§ 417.562 Weighting of direct services furnished by physicians and other practitioners.

(a) *Basic Rule.* For contract periods beginning before January 1, 1986, an organization may adjust ("weight") the statistics it uses to compute the apportionment of the costs of the direct professional covered Part B services of physicians and other health care personnel furnished to different patient groups to reflect variations in complexity and time required to furnish the services. HCFA must approve the weighting in advance as set forth in paragraph (b) of this section.

(b) *Basis for HCFA approval.* HCFA will approve weighting if—

(1) The weighting is based on data acceptable to HCFA;

(2) All services (covered and noncovered) used in the apportionment ratio (that is, those furnished to Medicare enrollees, to other enrollees, and to nonenrolled patients) are weighted on the same basis;

(3) The organization uses only one weighting method at a time;

(4) The weighting is applied only to services furnished to Medicare enrollees—

(i) In which there is a face-to-face contact between the enrollee and the health care personnel; and

(ii) In an ambulatory health care setting that is not a provider (for example, a medical center or clinic);

(5) The payment limitations set forth in § 417.560(c) are applied to the services, if applicable; and

(6) In the case of covered Part B services furnished under arrangements, apportionment is on the basis of services as specified in § 417.560(b).

(c) *Weighting procedure.* Weighting is accomplished by adjusting the statistics in which weighting is permissible. These weighted statistics are used to compute the weighted apportionment ratio that is applied to the salaries, wages, incentive payments, fringe benefits, and other forms of compensation of those health care personnel who furnish services that involve face-to-face contact with patients. The organization may not weight—

(1) Costs related to equipment, medical records, and supplies;

(2) Other costs not related to the compensation for the direct professional services of physicians and other health care personnel; or

(3) Costs already apportioned by relative value units or some other apportionment method in which time or complexity is reflected in the apportionment statistic.

(d) *Limitations on payment for services-furnished under arrangement.* If payment is on a fee-for-service basis, time and complexity are recognized, subject to the payment limitation in § 417.560(c) but only to the extent that they are specific and reasonable elements of the amount that the organization has agreed to pay for the services.

§ 417.564 Apportionment and allocation of administrative and general costs.

(a) Enrollment, marketing, and other administrative and general costs of the organization that benefit the total enrolled population of the organization and are not directly associated with providing medical care must be apportioned on the basis of a ratio of Medicare enrollees to the total enrollment of the organization.

(b) Administrative and general costs that bear a significant relationship to the services furnished are not apportioned to Medicare directly. These costs include facility costs, interest expense, medical record costs, centralized purchasing costs, accounting and data processing costs, and the administrative and general costs that are not included in paragraph (a) of this section. These costs are allocated or distributed to the components of the organization and are then apportioned to Medicare in accordance with the rules described in §§ 417.552 through 417.560. The allocation or distribution process must be made as follows:

(1) If a separate entity or department of an organization performs administrative functions whose benefits can be quantitatively measured (such as centralized purchasing and data processing), the total allowable costs of this entity or department must be allocated or distributed to the components of the organization in reasonable proportion to the benefits received by these components.

(2) If a separate entity or department of an organization performs administrative functions whose benefits cannot be quantitatively measured (such as facility costs), the total allowable costs of this entity or department

must be allocated or distributed to the components of the organization on the basis of a ratio of total incurred and distributed costs per component to the total incurred and distributed costs for all components.

§ 417.566 Other methods of allocation and apportionment.

(a) *Justification.* A method of apportionment or allocation of costs, other than the methods prescribed in this subpart may be used if it results in a more accurate and equitable apportionment of allowable costs and is justifiable from an administrative and cost standpoint.

(b) *Required approval.* (1) An organization that desires to use an alternative method must submit a written request for HCFA approval at least 90 days before the beginning of the period for which the different method is to be used.

(2) If HCFA approves use of a different method, the organization may not revert to another method without first obtaining HCFA's approval.

§ 417.568 Adequate financial records, statistical data, and cost finding.

(a) *Maintenance of records.* (1) An organization must maintain sufficient financial records and statistical data for proper determination of costs payable by Medicare for covered services the organization furnished to its Medicare enrollees, either directly or under arrangements with others. These include accurate and sufficient detail of incurred costs and enrollment data.

(2) Unless otherwise provided for in this subpart, standardized definitions and accounting, statistics, and reporting practices that are widely accepted in the health care industry must be followed.

(b) *Provision of data.* (1) The organization must provide adequate cost and statistical data, based on its financial and statistical records, that can be verified by qualified auditors.

(2) The cost data must be based on an approved method of cost finding and, except as described in this paragraph, on the accrual method of accounting.

(3) For governmental institutions that use a cash basis of accounting, cost data based on this basis will be acceptable. However, only depreciation on capital assets, rather than the expenditure for the capital asset, is allowable.

(c) *Provider services furnished directly by the organization.* If provider services are furnished directly by the organization, the provider is subject to the cost-finding and cost-reporting requirements set forth in Parts 412 and 413 of this chapter. An approved cost-finding method described in § 413.24 of this chapter must be used to determine the actual cost of covered services furnished directly by the organization during its contract period.

(d) *Supplier services furnished directly by the organization.* If the organization furnishes Part B physician and supplier services directly, the organization must furnish statistics that indicate the frequency and type of service provided, in the form and detail prescribed by HCFA.

(e) *Part B physician and supplier services furnished through arrangement.* If the organization furnishes Part B physician and supplier services under arrangements with others, it must furnish to HCFA statistical, financial, and other information with respect to those services in the form and detail prescribed by HCFA.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34832, Sept. 30, 1986]

§ 417.570 Interim per capita payments.

(a) *Principle of payment.* (1) HCFA makes monthly advance payments equivalent to the organization's interim per capita rate for each beneficiary who is registered in HCFA records as a Medicare enrollee of the organization.

(2) Additional lump-sum payments may be made at other times during the contract period, at HCFA's discretion, to adjust the total amounts paid during the contract period to the level of incurred costs.

(b) *Determination of rate.* The interim per capita rate of payment is equal to the estimated per capita cost of providing covered services to the organization's Medicare enrollees, based upon the types and components of costs that are reimbursable under this part. The interim per capita rate is determined annually by HCFA on the basis of the organization's annual operating and enrollment forecast (as set forth in § 417.572) and may be revised during the contract period as explained in paragraphs (c) and (d) of this section.

(c) *Adjustments of payments.* In order to maintain the interim payments at the level of current reasonable costs, HCFA will adjust the interim per capita rate, to the extent necessary, on the basis of adequate data supplied by the organization in its interim estimated cost and enrollment reports or on other evidence showing that the rate based on actual costs is more or less than the current rate. Adjustments may also be made if there is—

(1) A change in the number of Medicare enrollees that affects the per capita rate;

(2) A material variation from the costs estimated when the annual operating budget was prepared; or

(3) A significant change in the use of covered services by the organization's Medicare enrollees.

(d) *Reduction of interim payments.* If the organization does not submit, on time, the reports and other data required to determine the proper amount of payment, HCFA may reduce interim payments to the extent appropriate, or may take any other action authorized under this part. An interim payment reduction remains in effect until HCFA can make a reasonable estimate of per capita costs.

§ 417.572 Budget and enrollment forecast and interim reports.

(a) *Annual submittal.* The organization must submit an annual operating budget and enrollment forecast, in the form and detail required by HCFA, at least 90 days before the beginning of each contract period. The forecast must be based on financial and statistical data and records that can be verified if HCFA requires a detailed review of supporting records. The data and records include, but are not limited to, all ledgers, books, records, and original evidence of costs, and statistical data used in the determination of reasonable cost.

(b) *Effect of failure to submit on time.* If the organization does not submit the budget and enrollment forecast on time, HCFA may—

(1) Establish an interim per capita rate of payment on the basis of the best available data and adjust payments on the basis of that rate until the required reports are submitted and a new interim per capita rate can be established; or

(2) If there is not enough data on which to base an interim per capita rate, inform the organization that interim payments will not be made until the required reports are submitted.

(c) *Interim cost reports.* (1) An organization must submit interim cost reports on a quarterly basis in the form and detail prescribed by HCFA. These interim cost reports must be submitted no later than 60 days after the close of each quarter of the contract period.

(2) HCFA may reduce the frequency of the reports required under paragraph (c)(1) of this section if HCFA determines that, on the basis of the organization's reporting experience, there is good cause to do so.

§ 417.574 Interim settlement.

(a) *Determination.* Within 30 days following the receipt of the organization's final interim cost and enrollment reports, HCFA will make an interim determination of the estimated amount payable to the organization for the reasonable cost of covered services furnished to its Medicare enrollees during the contract period. HCFA will base the determination on the interim cost report and enrollment data submitted by the organization, and any other relevant data HCFA finds appropriate. For this purpose, HCFA will accept costs as reported, subject to later review or audit, unless there are obvious errors or inconsistencies.

(b) *Payment.* Any difference between the total amount of interim payments and the amount found payable on the basis of the interim determination under paragraph (a) of this section, must be paid by the organization or will be paid by HCFA, whichever is appropriate, no later than 30 days after HCFA's determination.

§ 417.576 Final settlement.

(a) *General rule.* Final settlement and payment of amounts due the organization or the appropriate Medicare trust funds are made following the organization's submission and HCFA's review of an independently certified cost report and supporting documents as described in paragraph (b) of this section.

(b) *Certified cost report as basis for final settlement*—(1) *Timing of cost report.* The organization must submit to HCFA an independently certified cost report and supporting documents, in the form and detail required by HCFA, no later than 180 days after the end of each contract period, unless HCFA extends the period for good cause shown by the organization.

(2) *Content of cost report.* The cost report and supporting documents must include—

(i) The per capita costs incurred by the organization, including those of entities related to the organization by common ownership or control, in furnishing covered services to its Medicare enrollees, determined in accordance with §§ 417.532 through 417.568.

(ii) The organization's methods of apportioning cost among Medicare enrollees, other enrollees, and nonenrolled patients, in accordance with the reimbursement procedures specified in this subpart (and, as applicable, in Parts 412 and 413 of this chapter); and

(iii) Any other information required by HCFA.

(3) *Failure to report required financial information.* If the organization fails to submit the required cost report and supporting documents within 180 days after the end of the contract period, without having requested and received an extension of time for good cause shown, HCFA may—

(i) Consider the failure to report as evidence of likely overpayment; and

(ii) Initiate recovery of amounts previously paid, or reduce interim payments, or both.

(c) *Final determination and adjustment.* (1) After receipt of acceptable reports as specified in paragraph (b) of this section, HCFA determines the total reimbursement due the organization for providing covered services to its Medicare enrollees (which is subject to the audit provisions of this subpart) and makes a retroactive adjustment to bring interim payments into agreement with the reimbursable amount due the organization.

(2) A final settlement may be made with the organization even though a provider that is not owned or operated by the organization or related to the organization by common ownership or control and that provides services to the organization's Medicare enrollees has not had a final settlement with HCFA under Parts 412 and 413 of this chapter for services furnished by the provider to Medicare beneficiaries who are not enrolled in the organization. In this situation—

(i) HCFA must be satisfied that the costs of covered services furnished to the organization's Medicare enrollees, as shown in the reports specified in paragraph (b) of this section, are reasonable and that the interest of the Medicare program would best be served by not delaying final settlement with the organization until there is a final settlement with the provider for services furnished to Medicare beneficiaries not enrolled in the organization; and

(ii) Prompt settlement with the organization would be in the best interest of the Medicare program if, for instance, the provider's costs represent an insignificant amount of total reimbursement due to the organization; or if HCFA is satisfied that the provider's costs, as shown in the reports specified in paragraph (b) of this section, will not be modified, to any significant extent, by the final settlement with the provider under Parts 412 and 413 of this chapter.

(d) *Notice of amount of reimbursement.* The notice of amount of Medicare reimbursement—

(1) Explains HCFA's determination regarding total Medicare reimbursement due the organization for the contract period covered by the financial information specified in paragraph (b) of this section;

(2) Relates this determination to the organization's claimed total reimbursable cost for that period;

(3) Explains the amounts and reasons, by appropriate reference to law, regulations, and Medicare program

policy and procedures, if the determined amounts differ from the organization's claim; and

(4) Informs the organization of its right to a hearing in accordance with Subpart R of Part 405 of this chapter.

(e) *Basis for retroactive adjustment.* (1) HCFA's determination (as contained in the notice of amount of Medicare reimbursement) constitutes the basis for making retroactive adjustments to any Medicare payment made to the organization during the period to which the determination applies.

(2) Further payments to the organization may be withheld or offset in order to recover, or to aid in the recovery of, any overpayment identified in the determination as having been made to the organization, even if the organization requests a hearing under Subpart R of Part 405 of this chapter.

(3) Any withholding will continue until—

(i) The overpayment is liquidated;

(ii) The organization enters into an agreement with HCFA to refund the overpaid amount; or

(iii) HCFA, on the basis of subsequently acquired evidence, determines that there was no overpayment.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986]

RISK REIMBURSEMENT

§ 417.580 Basis and scope.

(a) *Basis.* Sections 417.582 through 417.598 implement those portions of section 1876 (a), (e), and (g) of the Act that pertain to the amount HCFA reimburses an organization for its Medicare enrollees who are enrolled on a risk basis.

(b) *Scope.* Sections 417.582 through 417.598 set forth—

(1) Method of payment;

(2) Procedures for determining the organization's payment rate; and

(3) Procedures for determining the additional benefits (and their value) the organization must provide to its Medicare enrollees.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.582 Definitions applicable to risk reimbursement.

As used in §§ 417.584 through 417.598—

Actuarial factors means factors such as the age, sex, and disability level distribution of the population and any other relevant factors that HCFA determines have a significant effect on the level of utilization and cost of health services.

Class of Medicare enrollees means a group of Medicare enrollees of an organization that HCFA constructs on the basis of actuarial factors.

Similar area means an area similar to the organization's geographic area but free from special characteristics that would distort the determination of the AAPCC.

U.S. per capita incurred cost means the average per capita cost, including intermediary or carrier administrative costs, incurred by Medicare, as determined on an accrual basis, for covered services furnished to Medicare beneficiaries nationwide during the most recent period for which HCFA has complete data.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.584 Payment to organizations with risk contracts.

Except as provided in §§ 417.440(d) and (e), 417.585 and 417.586, HCFA makes payments for covered services furnished to the organization's Medicare enrollees only to the organization.

(a) *Principle of payment.* HCFA makes monthly advance payments equivalent to the organization's per capita rate of payment for each beneficiary who is registered in HCFA records as a Medicare enrollee of the organization.

(b) *Determination of rate.* (1) The annual per capita rate of payment for each class of Medicare enrollees is equal to 95 percent of the AAPCC (as determined under the provisions of § 417.588) for that class of Medicare enrollees.

(2) HCFA furnishes each organization with its per capita rate of payment for each class of Medicare enrollees not later than 90 days before the

beginning of the organization's contract period.

(c) *Adjustments to payments.* If the organization's actual number of Medicare enrollees in each class differs from the number of individuals estimated to be enrolled for purposes of determining the amount of advance payment, HCFA will adjust the amount of payment made in subsequent months to take these enrollment changes into account.

(d) *Reduction of payments.* If an organization requests a reduction in its monthly payment in accordance with § 417.592(e), HCFA will reduce the amount of payment by the appropriate amount. Reductions in the monthly payment to an organization will also be made if the organization elects the hospital or SNF payment option described in § 417.586.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987]

§ 417.585 Exception for hospice care services.

(a) No payment is made to an organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter except for the portion of the payment applicable to the additional benefits described in § 417.592. No payment is made effective the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the enrollee resumes normal Medicare coverage.

(b) During the time the election is in effect, the organization may bill HCFA on a fee-for-service basis (subject to the usual Medicare rules of payment) for only the following covered Medicare services:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the organization and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which hospice care was elected or a condition related to the terminal condition.

(3) Services furnished after the revocation or expiration of the enrollee's hospice election until the full monthly capitation payments begin again.

(c) Payment for hospice care services furnished to Medicare enrollees of an organization are made to the hospice participating in Medicare elected by the enrollee.

§ 417.586 Organization option: Payment to hospitals and SNFs.

(a) *Election by organization.* (1) An organization may elect to have hospitals or SNFs that furnish inpatient services to its Medicare enrollees, or both of those types of providers, obtain payment directly from the provider's Medicare intermediary.

(2) If an organization wishes to elect either or both of these options, it must submit a written request to HCFA before the organization's contract period begins.

(3) The election of these payment options by the organization is binding for the entire contract period.

(b) *Payment by intermediary to the hospital or SNF.* (1) After an organization submits its request, HCFA pays the hospital or SNF through the provider's Medicare intermediary for the covered inpatient services furnished to the organization's Medicare enrollees.

(2) The payment made under paragraph (b)(1) of this section is equal to the payment made in accordance with the principles of reimbursement specified in Parts 412 and 413 of this chapter.

(c) *Reduction in organization's per capita payment.* (1) Each month HCFA will deduct from the organization's per capita payment described in § 417.584 an amount HCFA estimates it will be paying to hospitals or SNFs on behalf of the organization's Medicare enrollees and administrative costs HCFA incurs in making the payments to the hospitals or SNFs.

(2) The amount of deduction will be adjusted as necessary to allow HCFA to retain sufficient funds with which to pay the bills.

(d) *Retention of withheld funds.* If the contract between the organization and HCFA is terminated or not renewed, HCFA will retain the balance of the amounts withheld from the organization's per capita payment for three years after the expiration or termination of the contract.

(e) *Organization's liability.* In making an election under this section, the organization must agree to accept liability and to provide the additional necessary funds to HCFA if—

(1) During the contract period or in subsequent years, HCFA did not withhold sufficient funds to pay the bills of the organization's Medicare enrollees; or

(2) After HCFA returns any balance of amounts withheld to the organization, HCFA receives additional bills that cover services furnished to Medicare enrollees of the organization during its contract period.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986]

§ 417.588 Computation of adjusted average per capita cost (AAPCC).

(a) *Basic data.* In computing the AAPCC, HCFA uses the U.S. per capita incurred cost and adjusts it by the factors specified in paragraph (c) of this section resulting in an AAPCC for each class of Medicare enrollees.

(b) *Advance notice to the organization.* Before the beginning of a contract period, HCFA informs the organization of the specific adjustment factors it will use in computing the AAPCC.

(c) *Adjustment factors*—(1) *Geographic.* HCFA makes an adjustment to reflect the relative level of Medicare expenditures for beneficiaries who reside in the organization's geographic area (or a similar area). This adjustment is based on reimbursement for Medicare covered services and uses the most accurate and timely data that pertain to the organization's geographic area and that is available to HCFA when it makes the determination.

(2) *Enrollment.* A further adjustment is made by HCFA to remove the cost effect of all area Medicare beneficiaries who are enrolled in the organization or another eligible organization.

(3) *Age, sex, and disability status.* HCFA makes adjustments to reflect the age and sex distribution and the disability status of the organization's enrollees based on Medicare program experience and available data that indicate cost differences that result from those factors.

(4) *Other relevant factors.* If accurate data are available and appropriate, HCFA makes adjustments to reflect welfare and institutional status and other relevant factors.

§ 417.590 Computation of the average of the per capita rates of payment.

(a) *Computation by the organization.* As indicated in § 417.584(b), prior to the start of an organization's contract period, HCFA determines an organization's per capita rate of payment for each class of Medicare enrollees. For purposes of determining an organization's required additional benefits (see § 417.592), an organization must compute a weighted average of these per capita rates of payment based on the organization's anticipated enrollment distribution. This computation must be done separately for Part A and Part B enrollees and Part B-only enrollees and is subject to HCFA's review and approval.

(b) *Computation by HCFA.* If the organization claims to have insufficient enrollment experience to make the computation required by paragraph (a) of this section, and HCFA agrees with this claim, then HCFA will compute the average of the per capita rates of payment based on the best information available to HCFA, including the enrollment experience of other organizations that have contracted with HCFA to receive reimbursement on a risk basis.

§ 417.592 Determination of required additional benefits.

(a) *General consideration.* Except as provided in paragraph (e) of this section, if the organization's average of its per capita rates of payment as determined under § 417.590 is more than the organization's adjusted community rate (ACR) as determined under § 417.594, then the organization must provide its Medicare enrollees with additional benefits as described in paragraphs (b) and (c) of this section. This determination must be done separately for Part A and Part B enrollees and Part B-only enrollees.

(b) *Form of additional benefits.* The additional benefits are selected by the organization and may be—

(1) A reduction in the organization's premium or other charges made by the organization in the form of deductibles and coinsurance; or

(2) Health benefits beyond the required Part A and B services; or

(3) A combination of the benefits specified in paragraphs (b)(1) and (b)(2).

(c) *Value of additional benefits.* The additional benefits must be at least equal in value to the difference between the ACR and the average of the per capita rates of payment, unless—

(1) The organization requests a reduction in its monthly payment as provided in paragraph (e) of this section; or

(2) The organization requests that HCFA withhold in a benefit stabilization fund as provided in § 417.596, a part of the value of the additional benefits it is required to provide.

(d) *Notification to HCFA.* (1) The organization must notify HCFA not later than 45 days before the beginning of the contract period of its ACR and its weighted average of its per capita rates of payment (as computed under § 417.590) for the contract period.

(2) If the proposed ACR is less than the average of the per capita rates of payment to be made at the beginning of the contract period, the organization must provide HCFA with—

(i) A description of the additional benefits (as described in paragraph (b) of this section) the organization has elected to provide its Medicare enrollees; and

(ii) Supporting evidence to demonstrate that the selected additional benefits are at least equal in value to the difference between the organization's proposed ACR and the average of the per capita rates of payment.

(e) *Exception.* (1) If the organization's ACR is less than the average of the per capita rates of payment, the organization may request a reduction in its monthly payment from HCFA instead of offering its Medicare enrollees additional benefits.

(2) The reduction in the monthly payment must, over the course of the contract period, be equal in value to the difference between the proposed ACR and the average of the per capita rates of payment, or meet the requirements of § 417.442(b)(1)(ii).

§ 417.594 Computation of ACR.

(a) *General.* (1) Each organization must compute its own ACR. In computing the ACR, the organization calculates an initial rate (using the methods described in paragraph (b) of this section) that represents the organization's premium if it provided the Medicare covered services package to its general membership (that is, its non-Medicare enrollees). The organization then either adjusts that rate by the factors specified in paragraph (c) of this section or requests that HCFA adjust the rate in accordance with the procedures specified in paragraph (d) of this section.

(2) The organization or HCFA further reduces this rate by the actuarial value of applicable Medicare coinsurance and deductibles.

(3) Separate ACRs must be calculated for Part A and Part B enrollees and Part B-only enrollees.

(4) In calculating its initial rate, the organization must identify and take into account anticipated revenue from health insurance payors for those services for which Medicare is not the primary payor as described in § 417.528.

(b) *Initial rate calculation.* (1) The organization's initial rate is calculated, at the organization's election, using either—

(i) A community rating system as defined in § 110.105(b) of this title; or

(ii) A system, approved by HCFA, under which the organization develops an aggregate premium for all its enrollees that is weighted by the size of the various enrolled groups that compose the organization's enrollment.

(For purposes of this section, enrolled groups are defined as employee groups or other bodies of subscribers that purchase membership in the organization on a premium basis.)

(2) Regardless of which method the organization uses to calculate its ini-

tial rate, the initial rate must be equal to the premium the organization would charge its non-Medicare enrollees for the Medicare covered services.

(3) Except as provided in paragraph (b)(4) of this section, the organization must identify in its initial rate calculation, the following components whose rates must be consistent with rates used by the organization in calculating premiums for non-Medicare enrollees:

(i) Hospital services (services covered under Medicare Part A and Part B shown separately).

(ii) Physicians' services.

(iii) Other medical services (for example, X-ray and laboratory services).

(iv) Home health services.

(v) Out-of-plan claims for emergency services.

(vi) Skilled nursing care services.

(vii) Ambulance services.

(viii) Other Medicare covered services.

(ix) General and administrative.

(x) Noncovered Medicare services (for example, eyeglasses).

(xi) Services for which Medicare is the secondary payor.

(xii) Enrollee liabilities (for example, deductibles, coinsurance, or copayments) for covered services.

(4) An organization that does not usually separate its premium components as described in paragraph (b)(3) of this section may calculate its initial rate with the methods it uses for its other enrolled groups if the organization provides HCFA with the documentation necessary to support any adjustments the organization makes to the initial rate in accordance with paragraph (e) of this section.

(5) The initial rate calculation must not carry forward any losses experienced by the organization during prior contract periods. The organization must submit supporting documentation to assure HCFA that rates do not include past losses but only premiums for the price of additional benefits and services of the upcoming contract period.

(c) *Adjustment factors.* These factors are designed to adjust on a component basis the initial rate calculated under paragraph (b) of this section to reflect the utilization characteristics of the organization's Medicare enrollees. The organization may adjust the same service using more than one factor if the factors do not duplicate each other. The factors are as follows:

(1) *Unit of service.* If the organization purchases or identifies services on a unit of service basis and the unit of service is defined the same for all enrollees, the organization may make an adjustment in its initial rate to reflect the number of units of services furnished to its Medicare enrollees in comparison to those furnished to other enrollees.

(2) *Complexity or intensity of services.* (i) The organization may make an adjustment to reflect the differences in the complexity or intensity of services furnished to its Medicare enrollees if the calculation of its initial rate includes the elements of this adjustment.

(ii) If an organization cannot support an adjustment such as that described in paragraph (c)(2)(i) of this section, it may, for contract periods beginning before January 1, 1986, make an adjustment to the direct professional services of physicians and other health care personnel. This adjustment will reflect the difference in time of service furnished to the organization's Medicare enrollees if the calculation of the organization's initial rate includes the elements of this adjustment.

(3) *Supporting documentation.* All adjustments made by the organization must be accompanied by adequate supporting data. If an organization does not have sufficient enrollment experience to develop this data, it may, during its initial contract period, use documented statistics from a nationally recognized statistical source.

(d) *Adjustment by HCFA.* If the organization does not have adequate data to adjust the initial rate calculated under paragraph (b) of this section to reflect the utilization characteristics of its Medicare enrollees, HCFA will, at the organization's request, adjust the initial rate. HCFA will adjust the rate on the basis of differences in the utilization characteristics of—

(1) Medicare and non-Medicare enrollees in other eligible organizations; or

(2) Medicare beneficiaries in the organization's area, State, or the United States who are eligible to enroll in an eligible organization and other individuals in that same area, State, or the United States.

(e) *HCFA review.* (1) The organization's methodology and computation of its ACR are subject to review and approval by HCFA. When the organization submits the ACR computation, it must include adequate supporting data.

(2) If the organization is dissatisfied with a HCFA determination that the organization's ACR computation is not acceptable, the organization may, within 30 days after the date of receipt of notification of this determination, file a request for a hearing with HCFA. The request must state why the determination is incorrect and must be accompanied by any supporting evidence the organization wishes to submit. The hearing will be conducted by a hearing officer designated by HCFA under the hearing procedures described in §§ 405.1819 through 405.1833 of this chapter.

§ 417.596 Establishment of a benefit stabilization fund.

(a) *General.* For contract periods beginning before July 19, 1988, if an organization is required to provide its Medicare enrollees with additional benefits as described in § 417.592, the organization may request that HCFA withhold a part of its monthly per capita payment in a benefit stabilization fund. The fund will be used to prevent excessive fluctuation in the provision of those additional benefits in subsequent contract periods.

(b) *Notification to HCFA.* An organization's request to have monies withheld in a benefit stabilization fund must be made when the organization notifies HCFA under § 417.592(d) of its ACR and the average of its per capita rates of payment in preparation for its next contract period.

(c) *Limitations on the amounts withheld*—(1) *Limit per contract period.* Except as provided in paragraph (c)(3) of this section, HCFA will not withhold in a benefit stabilization fund more than 15 percent of the difference between an organization's ACR and the average of its per capita rates of payment for a given contract period.

(2) *Cumulative limit.* If HCFA has established a benefit stabilization fund for an organization, it will not approve a request for withholding made by that organization for a subsequent contract period that would cause the total value of the benefit stabilization fund to exceed 25 percent of the difference between the organization's ACR and the average of its per capita rates of payment for that subsequent contract period.

(3) *Exception.* HCFA may grant an exception to the limit described in paragraph (c)(1) of this section if an organization can demonstrate to HCFA's satisfaction that the value of the additional benefits it provides to its Medicare enrollees fluctuates substantially in excess of 15 percent from one contract period to another.

(d) *Financial management of benefit stabilization funds.* (1) The amounts withheld by HCFA for the purpose of establishing or maintaining a benefit stabilization fund are in the custody of the Federal Health Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

(2) The amounts withheld in a benefit stabilization fund are accounted for by HCFA in accounts in which interest does not accrue to the organization.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.597 Withdrawal from a benefit stabilization fund.

(a) *Notification to HCFA.* An organization's request to make a withdrawal from its benefit stabilization fund for use during a contract period must be made when the organization notifies HCFA of its ACR and the average of its per capita rates of payment for that contract period. In making its request, the organization must—

(1) Indicate how it intends to use the withdrawn amounts;

(2) Justify the need for the withdrawal in terms of stabilizing the additional benefits it provides to Medicare enrollees;

(3) Document the organization's experience with fluctuations of revenue

requirements relative to the additional benefits it provides to Medicare enrollees; and

(4) Document the organization's experience during the contract period previous to the one for which the withdrawal is requested to ensure that the organization will not be using the withdrawn amounts to refinance losses suffered during that previous contract period.

(b) *Criteria for HCFA approval.* HCFA will approve an organization's request for a withdrawal from its benefit stabilization fund for use during the next contract period only if—

(1) The organization's average of its per capita rates of payment for the next contract period is less than that of the previous contract period;

(2) The organization's ACR for the next contract period is significantly higher than that of the previous contract period;

(3) The organization's revenue requirements for the next contract period for providing the additional benefits it provided during the previous contract period is significantly higher than the requirements for that previous period and the ACR for the next contract period results in an additional benefits package that is less in total value than that of the previous contract period; or

(4) The organization underestimated the number of current nonrisk Medicare enrollees who enrolled in a plan for special supplemental benefits as described in § 417.444(b).

(c) *Basis for denial.* HCFA will not approve an organization's request for a withdrawal from its benefit stabilization fund if the withdrawal allows the organization to—

(1) Offer without charge the supplemental services it provides to its Medicare enrollees under the provisions of § 417.440 (b)(2) or (b)(3); or

(2) Refinance prior contract period losses or to avoid losses in the upcoming contract period.

(d) *Form of payment.* Payment of monies withdrawn from a benefit stabilization fund is made, in equal parts, as an additional amount to the monthly advance payment made to the organization under § 417.584 during the period of the contract.

(e) *Availability of a benefit stabilization fund.* (1) Amounts withheld in a benefit stabilization fund are available for use by an organization only for four years following the establishment of the fund.

(2) Any amounts remaining in a benefit stabilization fund after the period of availability described in paragraph (e)(1) of this section will revert to the Medicare Trust Funds in the proportions HCFA determines to be appropriate.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 51 FR 28574, Aug. 8, 1986]

§ 417.598 Annual enrollment reconciliation.

HCFA's payment to an organization may be subject to an enrollment reconciliation at least annually. HCFA will conduct this reconciliation as necessary to assure that the payments made do not exceed or fall short of the appropriate per capita rate of payment for each Medicare enrollee of the organization during the contract period. The organization must submit any information or reports required by HCFA to conduct the reconciliation.

BENEFICIARY APPEALS

§ 417.600 Scope.

Sections 417.600 through 417.638 establish procedures for the presentation and resolution of initial determinations, reconsiderations, hearings, Appeals Council reviews, court reviews, and finality of decisions, that are applicable in matters arising under section 1876 of the Act and this subpart. The grievance procedures established by organizations under § 417.436(a)(2) apply to all complaints that do not involve initial determinations. Those grievance procedures must provide to Medicare enrollees a thorough explanation of—

(a) The steps to follow in completing the procedure; and

(b) The time limits imposed on each step of the procedure.

§ 417.602 Definitions applicable to beneficiary appeals.

As used in §§ 417.604 through 417.638, unless the context indicates otherwise—

ALJ stands for administrative law judge.

Enrollee means a Medicare enrollee.

RRB stands for Railroad Retirement Board.

§ 417.604 General provisions.

(a) *Applicability.* (1) The appeals procedure described in §§ 417.604 through 417.638 pertain to disputes involving an initial determination, as defined in § 417.606, with which the enrollee is dissatisfied.

(2) Any determinations regarding items or services that were furnished by the organization, either directly or under arrangement, for which the enrollee has no further liability for payment are not subject to appeal.

(3) Services included in an optional supplemental plan (see § 417.440(b)(2)) are subject only to a grievance procedure under § 417.436(a)(2).

(4) Except as provided in § 417.610(b), physicians and other individuals who furnish items or services under arrangements with an organization have no right of appeal under this subpart.

(5) The provisions of Subpart R of 20 CFR Part 404 dealing with representation of parties under Title II of the Act are, unless otherwise provided in this subpart, also applicable to matters arising under section 1876 of the Act.

(b) *Responsibility for establishing appeals procedures.* (1) Except as provided in paragraph (b)(2) of this section, the provisions of §§ 417.604 through 417.638 apply equally to all enrollees regardless of the method of claims processing adopted by the organization. The organization is responsible for establishing and maintaining the appeals procedures that are specified in these sections.

(2) If a carrier or intermediary processes the claims for an organization's enrollees, the carrier or intermediary—

(i) Is acting in the place of the organization, except with regard to initial determinations as specified in § 417.606(a)(3); and

(ii) Acts for the organization with respect to the appeals procedures specified in §§ 417.604 through 417.638, except that § 417.620(b)(2) does not apply to a carrier or intermediary.

(c) *Written description of appeals procedure.* Each organization is responsible for ensuring that all enrollees are informed in writing of the appeals procedures that are available to them.

§ 417.606 Initial determinations.

(a) *Actions that are initial determinations.* An initial determination is a determination made by an organization, or carrier or intermediary acting for the organization, concerning the rights of an enrollee with regard to services payable by Medicare that are furnished by the organization. In addition, an initial determination is also any determination made with respect to—

(1) Reimbursement for emergency or urgently needed services;

(2) Any other health services furnished by a provider or supplier other than the organization that the enrollee believes—

(i) Are covered under Medicare; and

(ii) Should have been furnished, arranged for, or reimbursed by the organization.

(3) The organization's refusal to provide services that the enrollee believes should be furnished or arranged for by the organization and the enrollee has not received the services outside the organization.

(b) *Actions that are not initial determinations.* The following are not initial determinations for purposes of this subpart:

(1) A determination regarding items or services that were furnished by the organization, either directly or under arrangement, for which the enrollee has no further obligation for payment.

(2) A determination regarding items or services included in an optional supplemental plan (see § 417.440(b)(2)).

(c) *Relation to grievances.* A determination that is not an initial determination is subject only to a grievance procedure under § 417.436(a)(2).

§ 417.608 Notice of adverse initial determination.

(a) If an organization, carrier, or intermediary makes an initial determination that is partially or fully adverse to the enrollee, it must notify the enrollee of the determination within 60 days of receiving the enrollee's request for payment of services.

(b) The notice must—

(1) State the specific reasons for the determination; and

(2) Inform the enrollee of his or her right to reconsideration.

(c) The failure to provide the enrollee with timely notification of an adverse initial determination constitutes an adverse initial determination and may be appealed.

§ 417.610 Parties to the initial determination.

The parties to the initial determination are—

(a) The enrollee;

(b) An assignee of the enrollee (that is, a physician or other supplier who accepts assignment for services furnished to an enrollee that are not covered by the organization's plan);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other entity determined to have an appealable interest in the proceeding.

§ 417.612 Effect of initial determination.

The initial determination is final and binding on all parties unless it is reconsidered in accordance with §§ 417.614 through 417.626, or revised in accordance with § 417.638.

§ 417.614 Right to reconsideration.

Any party to an initial determination who is dissatisfied with that determination may request a reconsideration of the determination after reopening in accordance with the procedures of § 417.616.

§ 417.616 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with—

(1) The organization, carrier, or intermediary that made the initial determination;

(2) An SSA office; or

(3) In the case of a qualified railroad retirement beneficiary, an RRB office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, the request for reconsideration must be filed within 60 days from the date of the notice of the initial determination.

(c) *Extension of time to file a request*—(1) *Rule.* If good cause is shown, the organization, carrier, or intermediary that made the initial determination may extend the time for filing the request for reconsideration.

(2) *Method of requesting an extension.* If the time limit in paragraph (b) of this section has expired, a party to the initial determination may file a request to extend the time to file a request for reconsideration with the organization, carrier, intermediary, HCFA, SSA, or, in the case of a qualified railroad retirement beneficiary, an RRB office. The request to extend the time limit must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed timely.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the initial determination as described in § 417.610, and any other person or entity whose rights with respect to the initial determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawal of request.* A request for reconsideration may be withdrawn by the party who filed the request. The request for withdrawal must be filed at one of the places specified in paragraph (c)(2) of this section.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.618 Opportunity to submit evidence.

The organization, carrier, or intermediary must provide the parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing.

§ 417.620 Responsibility for reconsideration.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, the entity that made the initial determination is the entity that reconsiders it.

(b) *Exception.* If the organization made the initial determination or the issue is the organization's refusal to furnish or arrange for requested services, the organization or HCFA makes the reconsidered determination, as follows:

(1) *Favorable determination by the organization.* If the organization can make a reconsidered determination completely favorable to the enrollee, it issues a reconsidered determination.

(2) *Unfavorable recommendation by the organization.* If the organization recommends partial or complete affirmation of the initial adverse determination, the organization must prepare a written explanation and forward the entire case file to HCFA, which makes a reconsidered determination.

§ 417.622 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the initial determination, the evidence and findings upon which it was based, and any other evidence submitted by the parties, or obtained by HCFA, the organization, or the carrier or intermediary; and

(b) Is made by a person or persons who were not involved in making the initial determination.

§ 417.624 Notice of reconsidered determination.

(a) *Responsibility for notice.* The entity that makes the reconsidered determination is responsible for mailing notice to the parties and, if that entity is not HCFA, for sending a copy to HCFA.

(b) *Content of notice.* The notice must—

(1) State the specific reasons for the reconsidered determination;

(2) Inform the party of his or her right to a hearing if the amount in controversy is $100 or more; and

(3) Describe the procedures that the party must follow to obtain a hearing.

§ 417.626 Effect of reconsidered determination.

A reconsidered determination is final and binding on all parties unless a request for a hearing is filed in accordance with the provisions of § 417.632, or unless it is revised in accordance with § 417.638.

§ 417.628 Hearings: General.

Unless otherwise provided in this subpart, regulations at 20 CFR 404.929 through 404.961 dealing with the conduct of hearings are also applicable to hearings arising under this subpart.

§ 417.630 Right to a hearing.

Any party to the reconsideration who is dissatisfied with the reconsidered determination has a right to a hearing if the amount in controversy is $100 or more. The amount in controversy is computed in accordance with § 405.740 of this chapter for Part A services and § 405.820(b) of this chapter for Part B services. When the basis for the appeal is the refusal of services, the projected value of those services must be used in computing the amount in controversy.

§ 417.632 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed at one of the places specified in § 417.616(a).

(b) *Time for filing a request.* Except when the time is extended by a presiding officer as provided in 20 CFR 404.933(c), a request for a hearing must be filed within 60 days of the date of the notice of reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be the parties to the reconsideration as described in § 417.616(d), and any other person or entity whose rights with respect to the reconsidered determination may be affected by the hearing, as determined by the ALJ. The organization must be made a party to the hearing; however, the organization does not have a right to request a hearing. Fees for any services provided by a representative appointed on behalf of the organization are not subject to section 206 of the Act, which governs appointment of representatives and payment of fees to representatives.

(d) *Dismissal of request for hearing when amount in controversy is less than $100.* The ALJ makes the determination as to whether the amount in controversy is $100 or more. The ALJ will dismiss the request for a hearing if the request plainly shows that less than $100 is in controversy. If a hearing is held and the ALJ finds that the amount in controversy is less than $100, he or she will dismiss the request for hearing and will not rule on the substantive issues involved in the appeal.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.634 Appeals Council review.

Any party to the hearing, including the organization, who is dissatisfied with the hearing decision, may request the Appeals Council to review the ALJ's decision or dismissal. Provisions regarding Appeals Council review are contained in 20 CFR 404.967 through 404.983.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985]

§ 417.636 Court review.

(a) *Review of ALJ's decision.* A party or the organization may request judicial review of an ALJ's decision if—

(1) The Appeals Council denied the party's or the organization's request for review; and

(2) The amount in controversy is $1,000 or more.

(b) *Review of Appeals Council decision.* A party or the organization may request judicial review of the Appeals Council decision if—

(1) It is the final decision of the Secretary; and

(2) The amount in controversy is $1,000 or more.

(c) *Request for review.* The civil action must be filed in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of the procedures to follow in requesting judicial review).

§ 417.638 Reopening determinations and decisions.

An initial, reconsidered, or revised determination made by an organization, carrier, intermediary, or HCFA, or a decision or revised decision of an ALJ or the Appeals Council, may be reopened in accordance with the provisions of § 405.750 of this chapter.

CONTRACT APPEALS

§ 417.640 Determinations subject to appeal.

Sections 417.640 through 417.694 establish the procedures for making and reviewing the following initial determinations:

(a) A determination that an eligible organization is not qualified to enter into a contract with HCFA under section 1876 of the Act.

(b) A determination that an eligible organization is qualified only for a reasonable cost contract.

(c) A determination to terminate, or to refuse to renew, a contract with an organization because—

(1) The organization has failed substantially to carry out the terms of the contract;

(2) The organization is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of section 1876 of the Act; or

(3) The organization no longer meets the applicable conditions necessary to qualify as an eligible organization under section 1876 of the Act and this subpart.

§ 417.642 Administrative actions that are not initial determinations.

Administrative actions that are not initial determinations under §§ 417.640 through 417.694 include, but are not limited to, HCFA's refusal to renew a contract with an organization when the refusal is not based on the causes specifed in § 417.640(c).

§ 417.644 Notice of initial determination.

(a) When HCFA makes an initial determination, it will notify the organization in writing.

(b) The notice specifies—

(1) The reasons for the determination; and

(2) The organization's right to request reconsideration.

(c) Notice of an initial determination specified in § 417.640 is mailed to the organization at least 90 days before the end of the contract period, or in the case of termination, at least 90 days before the effective date of the termination.

§ 417.646 Effect of initial determination.

The initial determination is final and binding on all parties unless—

(a) It is reconsidered in accordance with §§ 417.648 through 417.658;

(b) In the case of an initial determination described in § 417.640(c), a request for a hearing is filed; or

(c) It is revised as a result of a reopening under § 417.692.

§ 417.648 Right to request reconsideration.

An entity that is dissatisfied with an initial determination as described in § 417.640 (a) or (b) may request a reconsideration of the determination in accordance with the procedures specified in § 417.650.

§ 417.650 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any HCFA office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, the request for reconsideration must be filed within 60 days from the date of the notice of the initial determination.

(c) *Extension of time to file a request.* HCFA may, in response to a party's written petition showing good cause, accept a request for reconsideration after the expiration of the 60 day period.

(d) *Proper party to file a request.* Only an authorized official of the entity that was a party to an initial determination may file the request for reconsideration.

(e) *Withdrawal of a request.* A request for reconsideration may be withdrawn by the party who filed the request at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with HCFA. If HCFA approves, the request for reconsideration is withdrawn.

§ 417.652 Opportunity to submit evidence.

HCFA will provide the parties to the reconsideration reasonable opportunity to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 417.654 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the initial determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the entity subsequent to the initial determination; and

(b) Affirms, reverses, or modifies the initial determination.

§ 417.656 Notice of reconsidered determination.

Written notice of the reconsidered determination is mailed by HCFA to the party concerned and—

(a) Contains findings with respect to the eligible organization's qualifications to enter into a contract with HCFA under section 1876 of the Act;

(b) States the specific reasons for the reconsidered determination; and

(c) Informs the party of its right to a hearing if it is dissatisfied with the determination.

§ 417.658 Effect of reconsidered determination.

A reconsidered determination is final and binding on all parties unless a request for a hearing is filed in accordance with § 417.662 or it is revised in accordance with § 417.692.

§ 417.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) An entity that has been determined in a reconsidered determination to be unqualified to enter into a contract with HCFA under section 1876 of the Act.

(b) An eligible organization that has been determined in a reconsidered determination to be qualified only for a reasonable cost contract.

(c) An organization whose contract with HCFA has been terminated or has not been renewed as a result of an initial determination as provided in § 417.640(c).

§ 417.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the entity or organization that was the party to the determination under appeal. The request for a hearing must be filed with any HCFA office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, a request for a hearing must be filed within 60 days after the date of receipt of the notice of initial or reconsidered determination.

(c) *Extension of time to file a request.* If good cause is shown, the 60-day period to request a hearing may be extended by HCFA.

(d) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 417.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) HCFA.

§ 417.664 Postponement of effective date of initial determination.

When a request for a hearing with respect to an initial determination is filed timely—

(a) The effective date of the initial determination to terminate a contract with an organization will be postponed until a hearing decision is reached; and

(b) The current contract will be extended at the end of the contract period (in the case of a determination not to renew) only—

(1) If HCFA finds that an extension of the contract will be consistent with the purpose of section 1876 of the Act; and

(2) For such period as HCFA and the organization agree.

§ 417.666 Designation of hearing officer.

HCFA will designate a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 417.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, HCFA will designate another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted to HCFA.

§ 417.670 Time and place of hearing.

(a) The hearing officer will fix a time and place for the hearing and send written notice to the parties. The notice must also inform the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer will give the parties reasonable notice of any change in time or place of adjournment.

§ 417.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 417.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 417.672 may, on behalf of the represented party—

(1) Give or accept any notice or request pertinent to the proceedings set forth in this subpart;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 417.676 Conduct of hearing.

(a) The hearing will be open to the parties and to the public.

(b) The hearing officer will inquire fully into all the matters at issue and must receive in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The parties will be provided an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer will decide the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 417.678 Evidence.

The hearing officer will rule on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

§ 417.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives will be permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 417.682 Discovery.

(a) Prehearing discovery will be permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents will be provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 417.684 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

§ 417.686 Record of hearing.

(a) A complete record of the proceedings at the hearing will be made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

§ 417.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by HCFA in implementing that Act.

§ 417.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer will issue a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer will provide a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reopened and revised in accordance with § 417.692.

§ 417.692 Reopening of initial or reconsidered determination or decision of a hearing officer.

(a) *Initial or reconsidered determination.* An initial or reconsidered determination may be reopened and revised by HCFA upon its own motion within one year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. It may be reopened and revised by another hearing officer designated by HCFA if the hearing officer who issued the decision is unavailable.

(c) *Notices.* (1) The notice of reopening and of any revisions following the reopening will be mailed to the parties.

(2) The notice of revision will specify the reasons for revisions.

§ 417.694 Effect of revised determination.

The revision of an initial or reconsidered determination is final and binding unless a party files a written request for hearing of the revised determination in accordance with § 417.662.

Subpart D—Health Care Prepayment Plans

SOURCE: 50 FR 1375, Jan. 10, 1985, unless otherwise noted.

§ 417.800 Reimbursement of health care prepayment plans; definitions and basic rule.

(a) *Definitions.* As used in this subpart, unless the context indicates otherwise—

"Covered Part B services" means physicians' services, diagnostic X-ray tests, laboratory, other diagnostic tests, and any additional medical and other health services, that the HCPP furnishes to its Medicare enrollees.

"Health care prepayment plan" (HCPP) means an organization that—

(1) Is responsible for the organization, financing and delivery of covered Part B services to a defined population on a prepayment basis;

(2) Meets the conditions specified in paragraph (b) of this section; and

(3) Elects to be reimbursed on a reasonable cost basis.

"Medicare enrollee" means a beneficiary under Part B of Medicare who has been identified on HCFA records as an enrollee of the HCPP. "Reporting period" means the period specified by HCFA for which an HCPP must report its costs and utilization.

(b) *Qualifying conditions.* (1) Except as provided in paragraph (b)(2) of this section, an organization wishing to participate as an HCPP must—

(i) Enter into a written agreement with HCFA as specified in § 417.801;

(ii) Furnish physicians' services through its employees or under a formal arrangement with a medical group, independent practice association or individual physicians; and

(iii) Furnish covered Part B services to its Medicare enrollees through institutions, entities, and persons that have qualified under the applicable requirements of Title XVIII of the Social Security Act.

(2) An organization that, as of January 31, 1983, was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act, and that would not otherwise meet the conditions specified in paragraph (b)(1), may receive reimbursement on a reasonable cost basis as an HCPP, provided it files an agreement with HCFA as required by § 417.801.

(c) *Payment of reasonable cost.* (1) Except as otherwise provided in this subpart, HCFA pays an HCPP on the basis of the reasonable cost it incurs, as specified in §§ 417.530 through 417.576, for the covered Part B services furnished to its Medicare enrollees.

(2) In determining the amount due an HCPP for covered Part B services furnished its Medicare enrollees, HCFA deducts from the reasonable cost actually incurred by the HCPP an amount equal to the actuarial value of the deductible and coinsurance amount that would otherwise be applicable to those services if the Medicare enrollees who received the services had not been enrolled in the HCPP.

(d) *Covered services not reimbursed to an HCPP.* (1) Services reimbursed under Part A are not reimbursable to an HCPP. HCFA makes payment for these services directly to the hospital, or other provider of services, on a reasonable cost basis through the provider's Medicare fiscal intermediary (for more details, see Parts 412 and 413 of this chapter).

(2) Covered Part B services furnished by a provider of services to an HCPP's Medicare enrollees are not payable to the HCPP. HCFA makes payment for these services to the pro-

vider on behalf of the Medicare enrollee through the provider's Medicare fiscal intermediary. This requirement does not affect Medicare payment to the HCPP for physicians' services furnished to its Medicare enrollees for which the physicians are compensated by the HCPP.

(e) *Payment for services to nonenrollees.* HCFA makes payment to an HCPP for covered Part B services furnished by the HCPP to a Medicare beneficiary who is not enrolled in the HCPP if the beneficiary assigns his rights to payment in accordance with § 424.55 of this chapter. Payment is made on a reasonable charge basis through the HCPP's Medicare carrier.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 53 FR 6648, Mar. 2, 1988]

§ 417.801 Agreements between HCFA and health care prepayment plans.

(a) *General requirement.* (1) In order to participate and receive payment under the Medicare program as an HCPP as defined in § 417.800, an organization must enter into a written agreement with HCFA.

(2) An existing group practice prepayment plan (GPPP) that continues as an HCPP under this Subpart D must have entered into a written agreement with HCFA within 60 days of January 31, 1983.

(b) *Terms.* The agreement must provide that the HCPP agrees to—

(1) Maintain compliance with the requirements for participation and reimbursement on a reasonable cost basis of HCPPs as specified in § 417.800;

(2) Not charge the Medicare enrollee, as defined in § 417.800, a beneficiary, or any other person for items or services for which that individual is entitled to have payment made under the provisions of this part, except for any deductible or coinsurance amounts for which the individual is liable;

(3) Refund, as promptly as possible, any money incorrectly collected as charges or premiums, or in any other way from Medicare enrollees in the HCPP in accordance with the requirements specified in § 417.456;

(4) Not impose any limitations on the acceptance of Medicare enrollees or beneficiaries for care and treatment that it does not impose on all other individuals; and

(5) Consider any additional requirements that HCFA finds necessary or desirable for efficient and effective program administration.

(c) *Duration of agreement.* Except for the term of the initial agreement, the agreement is for a term of one year and may be renewed annually by mutual consent. The term of the initial agreement is set by HCFA.

(d) *Termination or nonrenewal of agreement by HCFA.* (1) HCFA may terminate or not renew an agreement if it determines that—

(i) The HCPP no longer meets the requirements for participation and reimbursement as an HCPP as specified in § 417.800;

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable HCFA regulations, or applicable provisions of the Medicare law; or

(iii) The HCPP undergoes a change in ownership as specified in §§ 417.520 through 417.523.

(2) HCFA will give notice of termination or nonrenewal to the HCPP at least 90 days before the effective date stated in the notice.

(e) *Termination or nonrenewal of agreement by HCPP.* (1) If an HCPP does not wish to renew its agreement at the end of the term, it must give written notice to HCFA at least 90 days before the end of the term of the agreement. If an HCPP wishes to terminate its agreement before the end of the term, it must file a written notice with HCFA stating the intended effective date of termination.

(2) HCFA may approve the termination date proposed by the HCPP, or set a different date no later than 6 months after that date. HCFA makes this decision based on a finding that termination on a specific date would not—

(i) Unduly disrupt the furnishing of services to the community serviced by the HCPP; or

(ii) Otherwise interfere with the efficient administration of the Medicare program.

§ 417.802 Allowable costs.

(a) *General rule.* The costs that are considered allowable for HCPP reimbursement are the same as those for reasonable cost HMOs and CMPs specified in §§ 417.530 through 417.550, except those in §§ 417.531, 417.532 (a)(3) and (c) through (g), 417.536 (l) and (m), 417.546, 417.548, and 417.550(b)(2).

(b) *Physicians' services and other Part B supplier services furnished under arrangements.*—(1) *Principle.* The amount paid by an HCPP for physicians' services and other Part B supplier services furnished under arrangements is an allowable cost to the extent it is reasonable.

(2) *Application: Payment on other than a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on other than a fee-for-service basis—

(i) Except as specified in paragraph (b)(2)(ii) of this section, the costs incurred by the HCPP may be considered reasonable if they—

(A) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(B) Are comparable to costs incurred for similar services furnished by similar physicians and other suppliers in the same or a similar locality.

(ii)(A) If a physician group to whom the HCPP makes payment compensates its physicians on a fee-for-service basis, the HCPP's payment to the group may not exceed the reasonable charges for those services, as defined in Subpart E of Part 405 of this chapter.

(B) Payment in excess of the limits specified in paragraph (b)(2)(ii)(A) of this section is allowable if the group has procedures under which members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In such cases, the amount paid by the HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

(3) *Application: Payment on a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on a fee-for-service basis—

(i) Except as specified in paragraph (b)(3)(ii) of this section, the costs incurred by the HCPP are considered reasonable if they do not exceed—

(A) The reasonable charges for those services, as defined in Subpart E of Part 405 of this chapter; and

(B) The amount that HCFA would pay for those services if they were furnished to beneficiaries who are not enrolled in the HCPP and who receive the services from sources other than providers of services or other entities that are reimbursed on a reasonable cost basis.

(ii) Payment to a physician group organized on an individual-practice basis is not subject to the paragraph (b)(3)(i) of this section if the group pays its physicians on a fee-for-service basis and has procedures under which the members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In these cases, the amount paid by an HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

§ 417.804 Cost apportionment.

(a) The HCPP follows the cost apportionment principles specified in §§ 417.552 through 417.566, except for provisions on provider costs and provisions on departmental apportionment.

(b) The HCPP may use a method for reporting costs that is approved by HCFA. HCFA bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

§ 417.806 Financial records, statistical data, and cost finding.

(a) The principles specified in § 417.568 will apply to HCPPs, except those in paragraph (c) of that section.

(b) The HCPP may use a method for reporting costs that is approved by HCFA. HCFA bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(c) An HCPP must permit the Department and the Comptroller General to audit or inspect any books and records of the HCPP and of any related organization that pertain to the determination of amounts payable for covered Part B services furnished its Medicare enrollees. For purposes of this requirement, the principles specified in § 417.486 apply to HCPPs.

§ 417.808 Interim per capita payments.

The HCPP follows the principles specified in §§ 417.570 and 417.572 on interim per capita payments, except for the following:

(a) When applying these principles to HCPPs, the term "reporting period" should be used instead of the term "contract period" contained in that section.

(b) An HCPP must submit to HCFA an annual operating budget and enrollment forecast, in the form and detail specified by HCFA, at least 60 days before the beginning of each reporting period. A reporting period must be 12 consecutive months, except that the HCPP's initial reporting period for participating in Medicare may be as short as 6 months or as long as 18 months.

(c) An HCPP must submit to HCFA an interim cost report and enrollment data applicable to the first 6-month period of the HCPP's reporting period in the form and detail specified by HCFA. The interim cost report must be submitted not later than 45 days after the close of the first 6-month period of the HCPP's reporting period.

(d) In lieu of an interim payment based on the actual monthly enrollment in an HCPP, HCFA and the HCPP may agree to a uniform monthly interim reimbursement rate for a reporting period. This interim rate is based on the HCPP's budget and enrollment forecast, if HCFA is satisfied that the rate is consistent with efficiency and economy, and will not result in excessive adjustment at the end of the reporting period.

§ 417.810 Final settlement.

(a) *General requirement.* HCFA and an HCPP must make a final settlement, and payment of amounts due either to the HCPP or to HCFA, following the submission and review of the HCPP's annual cost report and the supporting documents specified in paragraph (b) of this section.

(b) *Annual cost report as basis for final settlement*—(1) *Form and due date.* An HCPP must submit to HCFA a cost report and supporting documents in the form and detail specified by HCFA, no later than 120 days following the close of a reporting period.

(2) *Contents.* The report must include—

(i) The HCPP's per capita incurred costs of providing covered Part B services to its Medicare enrollees during the reporting period, including any costs incurred by another organization related to the HCPP by common ownership or control;

(ii) The HCPP's methods of apportioning costs among its Medicare enrollees, enrollees who are not Medicare beneficiaries, and other nonenrollees, including Medicare beneficiaries receiving health care services on a fee-for-service or other basis; and

(iii) Information on enrollment and other data as specified by HCFA.

(3) *Extension of time to submit cost report.* HCFA may grant an HCPP an extension of time to submit a cost report for good cause shown.

(4) *Failure to report required financial information.* If an HCPP does not submit the required cost report and supporting documents within the time specified in paragraph (b)(1) of this section, and has not requested and received an extension of time for good cause shown, HCFA may—

(i) Regard the failure to report this information as evidence of likely overpayment and reduce or suspend interim payments to the HCPP; and

(ii) Determine that amounts previously paid are overpayments, and make appropriate recovery.

(c) *Determination of final settlement.* Following the HCPP's submission of the reports specified in paragraph (b) of this section in acceptable form, HCFA makes a determination of the total reimbursement due the HCPP for the reporting period and the difference, if any, between this amount and the total interim payments made to the HCPP. HCFA sends to the HCPP a notice of the amount of reimbursement by the Medicare program. This notice—

(1) Explains HCFA's determination of total reimbursement due the HCPP for the reporting period; and

(2) Informs the HCPP of its right to have the determination reviewed at a hearing as provided in Part 405, Subpart R of this subchapter.

(d) *Payment of amounts due.* (1) Within 30 days of HCFA's determination, HCFA or the HCPP, as appropriate, will make payment of any difference between the total amount due and the total interim payments made to the HCPP by HCFA.

(2) If the HCPP does not pay HCFA within 30 days of HCFA's determination of any amounts the HCPP owes HCFA, HCFA may offset further payments to the HCPP to recover, or to aid in the recovery of, any overpayment identified in its determination.

(3) Any offset of payments HCFA makes under paragraph (d)(2) of this section will remain in effect even if the HCPP has requested a hearing on the determination under the provisions of Part 405, Subpart R of this chapter.

(e) *Tentative settlement.* (1) If a final settlement cannot be made within 90 days after the HCPP submits the report specified in paragraph (b) of this section, HCFA will make an interim settlement by estimating the amount payable to the HCPP.

(2) HCFA or the HCPP will make payment within 30 days of HCFA's determination under the tentative settlement of any estimated amounts due.

(3) The tentative settlement is subject to adjustment at the time of a final settlement.

PART 418—HOSPICE CARE

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AUTHORITY: Secs. 1102, 1811-1814, 1815(e), 1861-1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395c-1395f, 1395g(e), 1395x-1395cc, and 1395hh).

SOURCE: 48 FR 56026, Dec. 16, 1983, unless otherwise noted.

Subpart A—General Provision and Definitions

§ 418.1 Statutory basis.

This part implements section 1861(dd) of the Social Security Act. Section 1861(dd) specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. The following sections of the Act are also pertinent:

(a) Sections 1812(a) (4) and (d) of the Act specify eligibility requirements for the individual and the benefit periods.

(b) Section 1813(a)(4) of the Act specifies coinsurance amounts.

(c) Sections 1814(a)(8) and 1814(i) of the Act contain conditions and limitations on coverage of and reimbursement for hospice care.

(d) Sections 1862(a) (1), (6) and (9) of the Act establish limits on hospice coverage.

§ 418.2 Scope of part.

Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B specifies the eligibility requirements and the benefit periods. Subpart C specifies conditions of participation for hospices. Subpart D describes the covered services and specifies the limits on services covered as hospice care. Subpart E specifies the reimbursement methods and procedures. Subpart F specifies coinsurance amounts applicable to hospice care.

§ 418.3 Definitions.

For purposes of this part—

"Attending physician" means a physician who—

(a) Is a doctor of medicine or osteopathy; and

(b) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

"Bereavement counseling" means counseling services provided to the individual's family after the individual's death.

"Cap period" means the twelve-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in § 418.309.

"Carrier" means an organization that has a contract with HCFA to administer Medicare's supplementary medical insurance program.

"Election period" means one of three periods for which an individual may elect to receive Medicare coverage of hospice care. The periods consist of

two 90-day periods and one 30-day period.

"Employee" means an employee (defined by section 210(j) of the Act) of the hospice or, if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice unit. "Employee" also refers to a volunteer under the jurisdiction of the hospice.

"Freestanding hospice" means a hospice that is not part of any other type of participating provider.

"Hospice" means a public agency or private organization or subdivision of either of these that—

(a) Is primarily engaged in providing care to terminally ill individuals; and

(b) Meets the conditions specified in §§ 418.50 to 418.98 and has a valid provider agreement and if it is a freestanding hospice that provides inpatient care directly, meets the condition in § 418.100.

"Intermediary" means an organization that has a contract with the Secretary to administer the benefits covered by Medicare's hospital insurance program, including the benefits covered under this part.

"Physician" means physician as defined in § 410.20 of this chapter.

"Representative" means a person who is, because of the individual's mental or physical incapacity, authorized in accordance with State law to execute or revoke an election for hospice care or terminate medical care on behalf of the terminally ill individual.

"Social worker" means a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

"Terminally ill" means that the individual has a medical prognosis that his or her life expectancy is 6 months or less.

[48 FR 56026, Dec. 16, 1983, as amended at 52 FR 4499, Feb. 12, 1987]

Subpart B—Eligibility, Election and Duration of Benefits

§ 418.20 Eligibility requirements.

In order to be eligible to elect hospice care under Medicare, an individual must be—

(a) Entitled to Part A of Medicare; and

(b) Certified as being terminally ill in accordance with § 418.22.

§ 418.22 Certification of terminal illness.

(a) *Obtaining certification.* The hospice must obtain the certification that an individual is terminally ill in accordance with the following procedures:

(1) For the first 90-day period of hospice coverage, the hospice obtains, no later than two calendar days after hospice care is initiated, written certification statements signed by—

(i) The medical director of the hospice or the physician member of the hospice interdisciplinary group; and

(ii) The individual's attending physician if the individual has an attending physician.

(2) For the subsequent 90-day or 30-day period, the hospice obtains, no later than two calendar days after the beginning of that period, a written certification statement prepared by the medical director of the hospice or the physician member of the hospice's interdisciplinary group.

(b) *Certification statement.* The certification must include—

(1) The statement that the individual's medical prognosis is that his or her life expectancy is six months or less; and

(2) The signature(s) of the physician(s) required to certify the terminal illness under paragraph (a) of this section.

(c) *Maintaining a record.* The hospice maintains the certification statements.

§ 418.24 Election of hospice care.

(a) *Election statement.* If an individual who meets the eligibility requirements for hospice care elects to receive that care, he or she must file an election statement with a particular hospice. An election may also be filed by a representative as defined in § 418.3. The election statement must include the elements specified in § 418.26.

(b) *Sequence of election periods.* The two 90-day election periods must be used before the 30-day period.

(c) *Duration of election.* An election to receive hospice care will be considered to continue through the initial election period and through the subsequent election periods without a break in care as long as the individual—

(1) Remains in the care of a hospice; and

(2) Does not revoke the election under the provisions of § 418.28.

(d) *Effective date of election.* (1) An individual or representative may designate an effective date for the election period that begins with the first day of hospice care or any subsequent day of hospice care.

(2) An individual or representative may not designate an effective date that is earlier than the date that the election is made.

(e) *Waiver of other benefits.* An individual waives all rights to Medicare payments for the duration of the election of hospice care for the following services:

(1) Hospice care provided by a hospice other than the hospice designated by the individual (unless provided under arrangements made by the designated hospice).

(2) Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition or that are equivalent to hospice care except for services—

(i) Provided by the designated hospice;

(ii) Provided by another hospice under arrangements made by the designated hospice; and

(iii) Provided by the individual's attending physician if that physician is not an employee of the designated hospice or receiving compensation from the hospice for those services.

§ 418.26 Elements of the election statement.

The election statement must include the following:

(a) Identification of the particular hospice that will provide care to the individual.

(b) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(c) Acknowledgement that certain Medicare services are waived by the election.

(d) The effective date of the election.

(e) The signature of the individual or representative.

§ 418.28 Revoking the election of hospice care.

(a) An individual or representative may revoke the individual's election of hospice care at any time during an election period.

(b) To revoke the election of hospice care, the individual or representative must file a statement with the hospice that includes the following information:

(1) A signed statement that the individual or representative revokes the individual's election for Medicare coverage of hospice care for the remainder of that election period.

(2) The date that the revocation is to be effective. (An individual or representative may not designate an effective date earlier than the date that the revocation is made).

(c) An individual, upon revocation of the election of Medicare coverage of hospice care for a particular election period—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under § 418.24(e)(2); and

(3) May at any time elect to receive hospice coverage for any other hospice election periods that he or she is eligible to receive.

§ 418.30 Change of the designated hospice.

(a) An individual or representative may change, once in each election period, the designation of the particular hospice from which hospice care will be received.

(b) The change of the designated hospice is not a revocation of the election for the period in which it is made.

(c) To change the designation of hospice programs, the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

(1) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(2) The date the change is to be effective.

§ 418.32 Duration of hospice coverage under Medicare.

(a) *General rule.* Except as provided under paragraph (b) of this section, Medicare coverage of hospice care will end on September 30, 1986.

(b) *Exception.* Medicare coverage of hospice care will continue beyond September 30, 1986, for an individual who has an election in effect on that date. Medicare coverage of hospice care will continue for that individual until—

(1) The end of the election period in effect; and

(2) The end of any consecutive election period(s) that the individual would have been entitled to on September 30, 1986.

Subpart C—Conditions of Participation

§ 418.50 Condition of participation—General provisions.

(a) *Standard: Compliance.* A hospice must maintain compliance with the conditions in §§ 418.50 to 418.98. A freestanding hospice that provides inpatient services directly must also maintain compliance with the condition in § 418.100.

(b) *Standard: Required services.* A hospice must be primarily engaged in providing the care and services described in § 418.202, must provide bereavement counseling and must—

(1) Make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;

(2) Make all other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions; and

(3) Provide these services in a manner consistent with accepted standards of practice.

(c) *Standard: Disclosure of information.* The hospice must meet the disclosure of information requirements at § 420.206 of this chapter.

ADMINISTRATION

§ 418.52 Condition of participation—Governing body.

A hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospice's total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all services provided are consistent with accepted standards of practice.

§ 418.54 Condition of participation—Medical director.

The medical director must be a hospice employee who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of the hospice's patient care program.

§ 418.56 Condition of participation—Professional management.

Subject to the conditions of participation pertaining to services in §§ 418.80 and 418.90, a hospice may arrange for another individual or entity to furnish services to the hospice's patients. If services are provided under arrangement, the hospice must meet the following standards:

(a) *Standard: Continuity of care.* The hospice program assures the continuity of patient/family care in home, outpatient, and inpatient settings.

(b) *Standard: Written agreement.* The hospice has a legally binding written agreement for the provision of arranged services. The agreement includes at least the following:

(1) Identification of the services to be provided.

(2) A stipulation that services may be provided only with the express authorization of the hospice.

(3) The manner in which the contracted services are coordinated, supervised, and evaluated by the hospice.

(4) The delineation of the role(s) of the hospice and the contractor in the admission process, patient/family assessment, and the interdisciplinary group care conferences.

(5) Requirements for documenting that services are furnished in accordance with the agreement.

(6) The qualifications of the personnel providing the services.

(c) *Standard: Professional management responsibility.* The hospice retains professional management responsibility for those services and ensures that they are furnished in a safe and effective manner by persons meeting the qualifications of this part, and in accordance with the patient's plan of care and the other requirements of this part.

(d) *Standard: Financial responsibility.* The hospice retains responsibility for payment for services.

(e) *Standard: Inpatient care.* The hospice ensures that inpatient care is furnished only in a facility which meets the requirements in § 418.98 and its arrangement for inpatient care is described in a legally binding written agreement that meets the requirements of paragraph (b) and that also specifies, at a minimum—

(1) That the hospice furnishes to the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) That the inpatient provider has established policies consistent with those of the hospice and agrees to abide by the patient care protocols established by the hospice for its patients;

(3) That the medical record includes a record of all inpatient services and events and that a copy of the discharge summary and, if requested, a copy of the medical record are provided to the hospice;

(4) The party responsible for the implementation of the provisions of the agreement; and

(5) That the hospice retains responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

§ 418.58 Condition of participation—Plan of care.

A written plan of care must be established and maintained for each individual admitted to a hospice program, and the care provided to an individual must be in accordance with the plan.

(a) *Standard: Establishment of plan.* The plan must be established by the attending physician, the medical director or physician designee and interdisciplinary group prior to providing care.

(b) *Standard: Review of plan.* The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee and interdisciplinary group. These reviews must be documented.

(c) *Standard: Content of plan.* The plan must include an assessment of the individual's needs and identification of the services including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

§ 418.60 Condition of participation—Continuation of care.

A hospice may not discontinue or diminish care provided to a Medicare beneficiary because of the beneficiary's inability to pay for that care.

§ 418.62 Condition of participation—Informed consent.

A hospice must demonstrate respect for an individual's rights by ensuring that an informed consent form that specifies the type of care and services that may be provided as hospice care during the course of the illness has been obtained for every individual, either from the individual or representative as defined in § 418.3.

§ 418.64 Condition of participation—Inservice training.

A hospice must provide an ongoing program for the training of its employees.

§ 418.66 Condition of participation—Quality assurance.

A hospice must conduct an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of care provided, including inpatient care, home care and care provided under arrangements. The findings are used by the hospice to correct identified problems and to revise hospice policies if necessary. Those responsible for the quality assurance program must—

(a) Implement and report on activities and mechanisms for monitoring the quality of patient care;

(b) Identify and resolve problems; and

(c) Make suggestions for improving patient care.

§ 418.68 Condition of participation—Interdisciplinary group.

The hospice must designate an interdisciplinary group or groups composed of individuals who provide or supervise the care and services offered by the hospice.

(a) *Standard: Composition of group.* The hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice:

(1) A doctor of medicine or osteopathy.

(2) A registered nurse.

(3) A social worker.

(4) A pastoral or other counselor.

(b) *Standard: Role of group.* The interdisciplinary group is responsible for—

(1) Participation in the establishment of the plan of care;

(2) Provision or supervision of hospice care and services;

(3) Periodic review and updating of the plan of care for each individual receiving hospice care; and

(4) Establishment of policies governing the day-to-day provision of hospice care and services.

(c) If a hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.

(d) *Standard: Coordinator.* The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

§ 418.70 Condition of participation—Volunteers.

The hospice in accordance with the numerical standards, specified in paragraph (e) of this section, uses volunteers, in defined roles, under the supervision of a designated hospice employee.

(a) *Standard: Training.* The hospice must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.

(b) *Standard: Role.* Volunteers must be used in administrative or direct patient care roles.

(c) *Standard: Recruiting and retaining.* The hospice must document active and ongoing efforts to recruit and retain volunteers.

(d) *Standard: Cost saving.* The hospice must document the cost savings achieved through the use of volunteers. Documentation must include—

(1) The identification of necessary positions which are occupied by volunteers;

(2) The work time spent by volunteers occupying those positions; and

(3) Estimates of the dollar costs which the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) for the amount of time specified in paragraph (d)(2).

(e) *Standard: Level of activity.* A hospice must document and maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must document a continuing level of volunteer activity. Expansion of care and services achieved through the use of volunteers, including the type of services and the time worked, must be recorded.

(f) *Standard: Availability of clergy.* The hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request such visits and must advise patients of this opportunity.

§ 418.72 Condition of participation—Licensure.

The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations.

(a) *Standard: Licensure of program.* If State or local law provides for licensing of hospices, the hospice must be licensed.

(b) *Standard: Licensure of employees.* Employees who provide services must be licensed, certified or registered in accordance with applicable Federal or State laws.

§ 418.74 Condition of participation—Central clinical records.

In accordance with accepted principles of practice, the hospice must establish and maintain a clinical record for every individual receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.

(a) *Standard: Content.* Each clinical record is a comprehensive compilation of information. Entries are made for all services provided. Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice. Each individual's record contains—

(1) The initial and subsequent assessments;

(2) The plan of care;

(3) Identification data;

(4) Consent and authorization and election forms;

(5) Pertinent medical history; and

(6) Complete documentation of all services and events (including evaluations, treatments, progress notes, etc.).

(b) *Standard; Protection of information.* The hospice must safeguard the clinical record against loss, destruction and unauthorized use.

CORE SERVICES

§ 418.80 Condition of participation—Core services.

Except as permitted in § 418.83, a hospice must ensure that substantially all the core services described in §§ 418.82 through 418.88 are routinely provided directly by hospice employees. A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in §§ 418.82 through 418.88.

[52 FR 7416, Mar. 11, 1987]

§ 418.82 Condition of participation—Nursing services.

The hospice must provide nursing care and services by or under the supervision of a registered nurse.

(a) Nursing services must be directed and staffed to assure that the nursing needs of patients are met.

(b) Patient care responsibilities of nursing personnel must be specified.

(c) Services must be provided in accordance with recognized standards of practice.

§ 418.83 Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

(a) HCFA may approve a waiver of the requirement in § 418.80 for nursing services provided by a hospice which is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence that it was operational on or before January 1, 1983, and that it made a good faith effort to hire a sufficient number of nurses to provide services directly. HCFA bases its decision as to whether to approve a waiver application on the following:

(1) The current Bureau of the Census designations for determining non-urbanized areas.

(2) Evidence that a hospice was operational on or before January 1, 1983 including:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983;

(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983; and

(iii) Evidence that the hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

(3) Evidence that a hospice made a good faith effort to hire nurses, including:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts;

(ii) Job descriptions for nurse employees;

(iii) Evidence that salary and benefits are competitive for the area; and

(iv) Evidence of any other recruiting activities (e.g., recruiting efforts at health fairs and contacts with nurses at other providers in the area);

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for one year at a time.

(d) HCFA may approve a maximum of two one-year extensions for each initial waiver. If a hospice wishes to receive a one-year extension, the hospice must submit a certification to HCFA, prior to the expiration of the waiver period, that the employment market for nurses has not changed significantly since the time the initial waiver was granted.

[52 FR 7416, Mar. 11, 1987]

§ 418.84 Condition of participation—Medical social services.

Medical social services must be provided by a qualified social worker, under the direction of a physician.

§ 418.86 Condition of participation—Physician services.

In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

§ 418.88 Condition of participation—Counseling services.

Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, provided after the patient's death as well as dietary, spiritual and any other counseling services for the individual and family provided while the individual is enrolled in the hospice.

(a) *Standard: Bereavement counseling.* There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient). A special coverage provision for bereavement counseling is specified § 418.204(c).

(b) *Standard: Dietary counseling.* Dietary counseling, when required, must be provided by a qualified individual.

(c) *Standard: Spiritual counseling.* Spiritual counseling must include notice to patients as to the availability of clergy as provided in § 418.70(f).

(d) *Standard: Additional counseling.* Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice.

OTHER SERVICES

§ 418.90 Condition of participation—Other services.

A hospice must ensure that the services described in §§ 418.92 to 418.98 are provided directly by hospice employees or under arrangements made by the hospice as specified in § 418.56.

§ 418.92 Condition of participation—Physical therapy, occupational therapy, and speech-language pathology.

Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

§ 418.94 Condition of participation—Home health aide and homemaker services.

Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the patients. A home health aide is a person who meets the training, attitude and skill requirements specified in § 405.1227 of this chapter.

(a) *Standard: Supervision.* A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services.

(b) *Standard: Duties.* Written instructions for patient care are prepared by a registered nurse. Duties include, but may not be limited to, the duties specified in § 405.1227(a) of this chapter.

§ 418.96 Condition of participation—Medical supplies.

Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions.

(a) *Standard: Administration.* All drugs and biologicals must be administered in accordance with accepted standards of practice.

(b) *Standard: Controlled drugs in the patient's home.* The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

(c) *Standard: Administration of drugs and biologicals.* Drugs and biologicals are administered only by the following individuals:

(1) A licensed nurse or physician.

(2) An employee who has completed a State-approved training program in medication administration.

(3) The patient if his or her attending physician has approved.

(4) Any other individual in accordance with applicable State and local laws. The persons, and each drug and biological they are authorized to administer, must be specified in the patient's plan of care.

§ 418.98 Condition of participation—Short term inpatient care.

Inpatient care must be available for pain control, symptom management and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

(a) *Standard: Inpatient care for symptom control.* Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A hospice that meets the condition of participation for providing inpatient care directly as specified in § 418.100.

(2) A hospital or an SNF that also meets the standards specified in § 418.100 (a) and (f) regarding 24-hour nursing service and patient areas.

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An ICF that also meets the standards specified in § 418.100 (a) and (f) regarding 24-hour nursing service and patient areas.

(c) *Standard: Inpatient care limitation.* Except as provided in paragraph (d) of this section, the total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in any 12-month period preceding a certification survey in a particular hospice may not exceed 20 percent of the total number of hospice days for this group of beneficiaries.

(d) *Standard: Exemption from limitation.* Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation specified in paragraph (c).

FREESTANDING HOSPICE WITH INPATIENT UNIT

§ 418.100 Condition of participation for freestanding hospices providing inpatient care directly.

A freestanding hospice that provides inpatient care directly must comply with all of the following standards.

(a) *Standard: Twenty-four-hour nursing services.* (1) The facility provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medications, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) Each shift must include a registered nurse who provides direct patient care.

(b) *Standard: Disaster preparedness.* The hospice has an acceptable written plan, periodically rehearsed with staff, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

(c) *Standard: Health and safety laws.* The hospice must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating—

(1) Construction, maintenance, and equipment for the hospice;

(2) Sanitation;

(3) Communicable and reportable diseases; and

(4) Post mortem procedures.

(d) *Standard: Fire protection.* (1) Except as provided in paragraphs (d) (2) and (3) of this section, the hospice must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference)[1] that are applicable to hospices.

(2) In consideration of a recommendation by the State survey agency, HCFA may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of the patients.

(3) Any hospice that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, as long as the hospice continues to remain in compliance with that edition of the Life Safety Code.

(4) Any facility of two or more stories that is not of fire resistive construction and is participating on the basis of a waiver of construction type or height, may not house blind, nonambulatory, or physically handicapped patients above the street-level floor unless the facility—

(i) Is one of the following construction types (as defined in the Life Safety Code):

(A) Type II (1, 1, 1)—protected noncombustible.

(B) Fully sprinklered Type II (0, 0, 0)—non-combustible.

(C) Fully sprinklered Type III (2, 1, 1)—protected ordinary.

(D) Fully sprinklered Type V (1, 1, 1)—protected wood frame; or

(ii) Achieves a passing score on the Fire Safety Evaluation System (FSES).

(e) *Standard: Patient areas.* (1) The hospice must design and equip areas for the comfort and privacy of each patient and family members.

(2) The hospice must have—

(i) Physical space for private patient/family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night;

(iii) Accommodations for family privacy after a patient's death; and

(iv) Decor which is homelike in design and function.

(3) Patients must be permitted to receive visitors at any hour, including small children.

(f) *Standard: Patient rooms and toilet facilities.* Patient rooms are designed and equipped for adequate nursing care and the comfort and privacy of patients.

(1) Each patient's room must—

(i) Be equipped with or conveniently located near toilet and bathing facilities;

(ii) Be at or above grade level;

(iii) Contain a suitable bed for each patient and other appropriate furniture;

(iv) Have closet space that provides security and privacy for clothing and personal belongings;

(v) Contain no more than four beds;

(vi) Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multipatient room; and

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[1] See footnote to § 405.1134(a) of this chapter.

(vii) Be equipped with a device for calling the staff member on duty.

(2) For an existing building, HCFA may waive the space and occupancy requirements of paragraphs (f)(1) (v) and (vi) of this section for as long as it is considered appropriate if it finds that—

(i) The requirements would result in unreasonable hardship on the hospice if strictly enforced; and

(ii) The waiver serves the particular needs of the patients and does not adversely affect their health and safety.

(g) *Standard: Bathroom facilities.* The hospice must—

(1) Provide an adequate supply of hot water at all times for patient use; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(h) *Standard: Linen.* The hospice has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(i) *Standard: Isolation areas.* The hospice must make provision for isolating patients with infectious diseases.

(j) *Standard: Meal service, menu planning, and supervision.* The hospice must—

(1) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast;

(2) Procure, store, prepare, distribute, and serve all food under sanitary conditions;

(3) Have a staff member trained or experienced in food management or nutrition who is responsible for—

(i) Planning menus that meet the nutritional needs of each patient, following the orders of the patient's physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (9th ed., 1981) is available from the Printing and Publications Office, National Academy of Sciences, Washington, D.C. 20418); and

(ii) Supervising the meal preparation and service to ensure that the menu plan is followed; and

(4) If the hospice has patients who require medically prescribed special diets, have the menus for those patients planned by a professionally qualified dietitian and supervise the preparation and serving of meals to ensure that the patient accepts the special diet.

(k) *Standard: Pharmaceutical services.* The hospice provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility is responsible for drugs and biologicals for its patients, insofar as they are covered under the program and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate Federal, State, and local laws. (See § 405.1124(g), (h), and (i) of this chapter.)

(1) *Licensed pharmacist.* The hospice must—

(i) Employ a licensed pharmacist; or

(ii) Have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

(2) *Orders for medications.* (i) A physician must order all medications for the patient.

(ii) If the medication order is verbal—

(A) The physician must give it only to a licensed nurse, pharmacist, or another physician; and

(B) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.

(3) *Administering medications.* Medications are administered only by one of the following individuals:

(i) A licensed nurse or physician.

(ii) An employee who has completed a State-approved training program in medication administration.

(iii) The patient if his or her attending physician has approved.

(4) *Control and accountability.* The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility. Drugs are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

(5) *Labeling of drugs and biologicals.* The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

(6) *Storage.* In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit is kept readily available.

(7) *Drug disposal.* Controlled drugs no longer needed by the patient are disposed of in compliance with State requirements. In the absence of State requirements, the pharmacist and a registered nurse dispose of the drugs and prepare a record of the disposal.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983; 49 FR 23010, June 1, 1984, as amended at 53 FR 11509, Apr. 7, 1988]

Subpart D—Covered Services

§ 418.200 Requirements for coverage.

To be covered, hospice services must meet the following requirements. They must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions. The individual must elect hospice care in accordance with § 418.24 and a plan of care must be established as set forth in § 418.58 before services are provided. The services must be consistent with the plan of care. A certification that the individual is terminally ill must be completed as set forth in § 418.22.

§ 418.202 Covered services.

All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:

(a) Nursing care provided by or under the supervision of a registered nurse.

(b) Medical social services provided by a social worker under the direction of a physician.

(c) Physicians' services performed by a physician as defined in § 410.20 of this chapter except that the services of the hospice medical director or the physician member of the interdisciplinary group must be performed by a doctor of medicine or osteopathy.

(d) Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.

(e) Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital or SNF, that additionally meets the standards in § 418.100 (a) and (f) regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management.

inpatient care may also be furnished as a means of providing respite for the individual's family or other persons caring for the individual at home. Respite care must be furnished as specified in § 418.98(b). Payment for inpatient care will be made at the rate appropriate to the level of care as specified in § 418.302.

(f) Medical appliances and supplies, including drugs and biologicals. Only drugs as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment as described in § 410.38 of this chapter as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care.

(g) Home health aide services furnished by qualified aides as designated in § 418.94 and homemaker services. Home health aides may provide personal care services as described in § 409.33 (d) of this chapter. Aides may also perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing the bed or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in personal care, maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

(h) Physical therapy, occupational therapy and speech-language pathology services in addition to the services described in § 409.33 (b) and (c) of this chapter provided for purposes of symptom control or to enable the patient to maintain activities of daily living and basic functional skills.

[48 FR 56026, Dec. 16, 1983, as amended at 51 FR 41351, Nov. 14, 1986]

§ 418.204 Special coverage requirements.

(a) *Periods of crisis.* Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis as necessary to maintain an individual at home. Either homemaker or home health aide services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which the individual requires continuous care to achieve palliation or management of acute medical symptoms.

(b) *Respite care.* (1) Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual.

(2) Except as provided in paragraph (b)(3) of this section, respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time.

(3) Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation on the frequency and number of respite care days.

(c) *Bereavement counseling.* Bereavement counseling is a required hospice service but it is not reimbursable.

Subpart E—Reimbursement Methods

§ 418.301 Reimbursement for hospice care.

(a) Medicare payment for covered hospice care is made in accordance with the method set forth in § 418.302.

(b) Medicare reimbursement to a hospice in a cap period is limited to a cap amount specified in § 418.309.

§ 418.302 Payment procedures for hospice care.

(a) HCFA establishes payment amounts to reimburse specific categories of covered hospice care.

(b) Payment amounts are determined within each of the following categories:

(1) *Routine home care day.* A routine home care day is a day on which an individual who has elected to receive hospice care is at home and is not re-

ceiving continuous care as defined in paragraph (b)(2) of this section.

(2) *Continuous home care day.* A continuous home care day is a day on which an individual who has elected to receive hospice care is not in an inpatient facility and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Home health aide or homemaker services or both may also be provided on a continuous basis. Continuous home care is only furnished during brief periods of crisis as described in § 418.204(a) and only as necessary to maintain the terminally ill patient at home.

(3) *Inpatient respite care day.* An inpatient respite care day is a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.

(4) *General inpatient care day.* A general inpatient care day is a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.

(c) The payment amounts for the categories of hospice care are fixed payment rates that are calculated by HCFA in accordance with the procedures described in § 418.306. Payment rates are determined for the following categories:

(1) Routine home care.

(2) Continuous home care.

(3) Inpatient respite care.

(4) General inpatient care.

(d) The intermediary reimburses the hospice at the appropriate payment amount for each day for which an eligible Medicare beneficiary is under the hospice's care.

(e) The intermediary makes payment according to the following procedures:

(1) Payment is made to the hospice for each day during which the beneficiary is eligible and under the care of the hospice, regardless of the amount of services furnished on any given day.

(2) Payment is made for only one of the categories of hospice care described in § 418.302(b) for any particular day.

(3) On any day on which the beneficiary is not an inpatient, the hospice is paid the routine home care rate, unless the patient receives continuous care as defined in paragraph (b)(2) of this section for a period of at least 8 hours. In that case, a portion of the continuous care day rate is paid in accordance with paragraph (e)(4) of this section.

(4) The hospice payment on a continuous care day varies depending on the number of hours of continuous services provided. The continuous home care rate is divided by 24 to yield an hourly rate. The number of hours of continuous care provided during a continuous home care day is then multiplied by the hourly rate to yield the continuous home care payment for that day. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate.

(5) Subject to the limitations described in paragraph (f) of this section, on any day on which the beneficiary is an inpatient in an approved facility for inpatient care, the appropriate inpatient rate (general or respite) is paid depending on the category of care furnished. The inpatient rate (general or respite) is paid for the date of admission and all subsequent inpatient days, except the day on which the patient is discharged. For the day of discharge, the appropriate home care rate is paid unless the patient dies as an inpatient. In the case where the beneficiary is discharged deceased, the inpatient rate (general or respite) is paid for the discharge day. Payment for inpatient respite care is subject to the requirement that it may not be provided consecutively for more than 5 days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate.

(f) Payment for inpatient care is limited as follows: (1) The total payment to the hospice for inpatient care (general or respite) is subject to a limitation that total inpatient care days for Medicare patients not exceed 20 percent of the total days for which these patients had elected hospice care.

(2) At the end of a cap period, the intermediary calculates a limitation on

payment for inpatient care to ensure that Medicare payment is not made for days of inpatient care in excess of 20 percent of the total number of days of hospice care furnished to Medicare patients.

(3) If the number of days of inpatient care furnished to Medicare patients is equal to or less than 20 percent of the total days of hospice care to Medicare patients, no adjustment is necessary. Overall payments to a hospice are subject to the cap amount specified in § 418.309.

(4) If the number of days of inpatient care furnished to Medicare patients exceeds 20 percent of the total days of hospice care to Medicare patients, the total payment for inpatient care is determined in accordance with the procedures specified in paragraph (f)(5) of this section. That amount is compared to actual payments for inpatient care, and any excess reimbursement must be refunded by the hospice. Overall payments to the hospice are subject to the cap amount specified in § 418.309.

(5) If a hospice exceeds the number of inpatient care days described in paragraph (f)(4), the total payment for inpatient care is determined as follows:

(i) Calculate the ratio of the maximum number of allowable inpatient days to the actual number of inpatient care days furnished by the hospice to Medicare patients.

(ii) Multiply this ratio by the total reimbursement for inpatient care made by the intermediary.

(iii) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(iv) Add the amounts calculated in paragraphs (f)(5)(ii) and (iii) of this section.

§ 418.304 Payment for physician services.

(a) The following services performed by hospice physicians are included in the rates described in § 418.302:

(1) General supervisory services of the medical director.

(2) Participation in the establishment of plans of care, supervision of care and services, periodic review and updating of plans of care, and establishment of governing policies by the physician member of the interdisciplinary group.

(b) For services not described in paragraph (a) of this section, a specified Medicare contractor pays the hospice an amount equivalent to 100 percent of the physician's reasonable charge for those physician services furnished by hospice employees or under arrangements with the hospice. Reimbursement for these physician services is included in the amount subject to the hospice payment limit described in § 418.309. Services furnished voluntarily by physicians are not reimbursable.

(c) Services of the patient's attending physician, if he or she is not an employee of the hospice or providing services under arrangements with the hospice, are not considered hospice services and are not included in the amount subject to the hospice payment limit described in § 418.309. These services are paid by the carrier under the procedures in Subparts D or E, Part 405 of this chapter.

§ 418.306 Determination of payment rates.

(a) HCFA calculates payment rates for each of the categories of hospice care described in § 418.302(c).

(b) Each rate is equal to a prospectively determined amount which HCFA estimates equals the costs incurred by hospice generally in efficiently providing that type of hospice care to Medicare beneficiaries.

(c) The rates are adjusted by the intermediary to reflect local differences in wages.

(d) HCFA will publish as a notice in the FEDERAL REGISTER any proposal to change the payment rates or the methodology for determining those rates.

§ 418.307 Periodic interim payments.

Subject to the provisions of § 413.64(h) of this chapter, a hospice may elect to receive periodic interim payments effective with claims received on or after July 1, 1987.

[53 FR 1628, Jan. 21, 1988]

§ 418.308 Limitation on the amount of hospice payments.

(a) Except as specified in paragraph (b) of this section, the total Medicare payment to a hospice for care furnished during a cap period is limited by the hospice cap amount specified in § 418.309.

(b) Until October 1, 1986, payment to a hospice that began operation before January 1, 1975 is not limited by the amount of the hospice cap specified in § 418.309.

(c) The intermediary notifies the hospice of the determination of program reimbursement at the end of the cap year in accordance with procedures similar to those described in § 405.1803 of this chapter.

(d) Payments made to a hospice during a cap period that exceed the cap amount are overpayments and must be refunded.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

§ 418.309 Hospice cap amount.

The hospice cap amount is calculated using the following procedures:

(a) The cap amount is $6,500 per year and is adjusted for inflation or deflation for cap years that end after October 1, 1984, by using the percentage change in the medical care expenditure category of the Consumer Price Index (CPI) for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from March 1984 to the fifth month of the cap year. The cap year runs from November 1 of each year until October 31 of the following year.

(b) Each hospice's cap amount is calculated by the intermediary by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries who elected to receive hospice care from that hospice during the cap period. For purposes of this calculation, the number of Medicare beneficiaries includes—

(1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with § 418.24, from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).

(2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total stay in all hospices that was spent in that hospice. (The hospice can obtain this information by contacting the intermediary.)

§ 418.310 Reporting and recordkeeping requirements.

Hospices must provide reports and keep records as the Secretary determines necessary to administer the program.

§ 418.311 Administrative appeals.

A hospice that believes its payments have not been properly determined in accordance with these regulations may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) if the amount in controversy is at least $1,000 or $10,000, respectively. In such a case, the procedure in 42 CFR Part 405, Subpart R, will be followed to the extent that it is applicable. The PRRB, subject to review by the Secretary under § 405.1874 of this chapter, shall have the authority to determine the issues raised. The methods and standards for the calculation of the payment rates by HCFA are not subject to appeal.

Subpart F—Coinsurance

§ 418.400 Individual liability for coinsurance for hospice care.

An individual who has filed an election for hospice care in accordance with §418.24 is liable for the following coinsurance payments. Hospices may charge individuals the applicable coinsurance amounts.

(a) *Drugs and biologicals.* An individual is liable for a coinsurance payment for each palliative drug and biological prescription furnished by the hospice while the individual is not an inpatient. The amount of coinsurance for each prescription approximates 5 percent of the cost of the drug or biological to the hospice determined in accordance with the drug copayment schedule established by the hospice, except that the amount of coinsurance for each prescription may not exceed $5. The cost of the drug or biological may not exceed what a prudent buyer would pay in similar circumstances. The drug copayment schedule must be reviewed for reasonableness and approved by the intermediary before it is used.

(b) *Respite care.* (1) The amount of coinsurance for each respite care day is equal to 5 percent of the payment made by HCFA for a respite care day.

(2) The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began.

(3) The individual hospice coinsurance period—

(i) Begins on the first day an election filed in accordance with § 418.24 is in effect for the beneficiary; and

(ii) Ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

§ 418.402 Individual liability for services that are not considered hospice care.

Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in § 418.400, that are considered covered hospice care (as described in § 418.202). The individual is liable for the Medicare deductibles and coinsurance payments and for the difference between the reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care. Examples of services not considered hospice care include: Services furnished before or after a hospice election period; services of the individual's attending physician, if the attending physician is not an employee of or working under an arrangement with the hospice; or Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition.

§ 418.405 Reduction of Medicare reimbursement by individual coinsurance liability.

The Medicare payment rates established by HCFA in accordance with § 418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when determining the payment rates, HCFA offsets the estimated cost of services by an estimate of average coinsurance amounts hospices collect.

PART 420—PROGRAM INTEGRITY: MEDICARE

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AUTHORITY: Secs. 1102, 1124, 1126, 1866, and 1871, of the Social Security Act (42 U.S.C. 1302, 1320a-3, 1320a-5, 1395cc, and 1395hh).

SOURCE: 44 FR 31142, May 30, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 420.1 Scope and purpose.

This part sets forth requirements for Medicare providers, intermediaries, and carriers to disclose ownership and control information. It also deals with access to records pertaining to certain contracts entered into by Medicare providers. These rules are aimed at protecting the integrity of the Medicare program. The statutory basis for these requirements is explained in each of the other subparts.

[51 FR 34787, Sept. 30, 1986]

§ 420.3 Other related regulations.

(a) *Appeals procedures.* Part 498 of this chapter sets forth the appeals procedures available to providers whose provider agreements HCFA terminates for failure to comply with the disclosure of information requirements set forth in Subpart C of this part.

(b) *Exclusion, termination, or suspension.* Part 1001 of this title sets forth the rules applicable to exclusion, termination, or suspension from the Medicare program because of fraud or abuse or conviction of program-related crimes.

[51 FR 34787, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart B—[Reserved]

Subpart C—Disclosure of Information

SOURCE: 44 FR 41642, July 17, 1979, unless otherwise noted.

§ 420.200 Purpose.

This subpart implements sections 1124, 1126, 1861, and 1866 of the Social Security Act. It sets forth requirements for providers, intermediaries, and carriers to disclose ownership and control information. It also sets forth requirements for disclosure of information on a provider's owners and other persons convicted of criminal offenses against Medicare, Medicaid, or the title XX services program.

§ 420.201 Definitions.

As used in this subpart unless the context indicates otherwise:

"Agent" means any person who has been delegated the authority to obligate or act on behalf of a provider.

"Disclosing entity" means:

(1) A provider of services, an independent clinical laboratory, a renal disease facility, a rural health clinic, or a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act); and

(2) A carrier or other agency or organization that is acting as a fiscal intermediary or agent for one or more providers of services for purposes of Part A or Part B of Medicare.

"Other disclosing entity" means any other Medicare disclosing entity and any entity that does not participate in Medicare, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XIX, or XX of the Act. This includes:

(1) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services for which payment may be claimed by the entity under any plan or program established under title V of the Social Security Act or under an approved State Medicaid plan;

(2) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which payment may be claimed by the entity under an approved State plan and services program under title XX of the Act; or

(3) A Medicaid fiscal agent.

"Group of practitioners" means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

"Indirect ownership interest" means any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

"Managing employee" means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the institution, organization, or agency.

"Ownership interest" means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

"Person with an ownership or control interest" means a person or corporation that—

(1) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(2) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(5) Is an officer or director of a disclosing entity that is organized as a corporation; or

(6) Is a partner in a disclosing entity that is organized as a partnership.

"Significant business transaction" means any business transaction or series of transactions during any one fiscal year, the total of which exceeds the lesser of $25,000 and 5 percent of the total operating expenses of the provider.

"Subcontractor" means—

(1) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(2) An individual, agency, or organization with which an intermediary or carrier has entered into a contract, agreement, purchase order or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicare agreement.

"Supplier" means an individual, agency, or organization from which a provider purchases goods and services used in carrying out its responsibilities under Medicare (e.g. a commercial laundry, a manufacturer of hospital beds, or a pharmaceutical firm).

"Wholly owned supplier" means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

§ 420.202 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine the percentage of ownership interest in any mortgage, deed of trust, note, or other obligation, the percentage of interest owned in obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 420.203 Disclosure of hiring of intermediary's former employees.

A provider must notify the Secretary promptly if it, or its home office (in the case of a chain organization), employs or obtains the services of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which currently serves, or at any time during the preceding year, served as a Medicare fiscal intermediary or carrier for the provider. "Similar capacity" means the performance of essentially the same work functions as those of a manager, accountant, or auditor even though the individual is not so designated by title.

§ 420.204 Principals convicted of a program-related crime.

(a) *Information required.* Prior to the Secretary's acceptance of a provider agreement, or at any time upon written request by the Secretary, the provider must furnish the Secretary with the identity of any person who has an ownership or control interest in the provider, or who is an agent or managing employee of the provider, and has been convicted of a criminal offense relating to involvement in Medicare, Medicaid, or the title XX services program since the inception of those programs.

(b) *Refusal to enter into or renew agreement.* The Secretary may refuse to enter into or renew an agreement with a provider of services if any person who has an ownership or control interest in the provider, or who is an agent or managing employee, has been convicted of a criminal offense related to the involvement of that person in Medicare, Medicaid, or the title XX services program. In making this decision, the Secretary will consider the facts and circumstances of the specific case, including the nature and severity of the crime and the extent to which it adversely affected beneficiaries and the programs involved. The Secretary will also consider whether he has been given reasonable assurance that the person will not commit any further criminal offense against the programs.

(c) *Notification of Inspector General.* The Secretary will promptly notify the Inspector General of the Department of receipt of any application or request for participation, certification, or recertification that identifies any person described in paragraph (a) of this section and of the action taken on that application or request.

(Secs. 1102, 1124, 1126, 1861(j)(11), 1866(a), 1866(b)(2), 1902(a)(38), 1903(i)(2), and 1903(n) of the Social Security Act; 42 U.S.C. 1302, 1320a-3, 1320a-5, 1395x(j)(11), 1395cc(a), 1395cc(b)(2), 1396a(a)(38), 1396b(i)(2), and 1396b(n))

[44 FR 41642, July 17, 1979, as amended at 45 FR 30634, May 9, 1980]

§ 420.205 Disclosure by providers of business transaction information.

A provider must submit to the Secretary, within 35 days after the date of a written request, full and complete information on—

(a) The ownership of a subcontractor with whom the provider has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000; and

(b) Any significant business transactions between the provider and any wholly owned supplier or between the provider and any subcontractor, during the 5 year period ending on the date of the request.

§ 420.206 Disclosure of persons having ownership, financial, or control interest.

(a) *Information that must be disclosed.* A disclosing entity must submit the following information in the manner specified in paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the entity or in any subcontractor in which the entity has a direct or indirect ownership interest totaling 5 percent or more.

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which any person with an ownership or control interest in the disclosing entity also has an ownership or control interest. This requirement applies to the extent the entity can obtain the information by requesting it in writing from the person. The disclosing entity must—

(i) Keep copies of all these requests and the responses to them;

(ii) Make them available to the Secretary or the Medicaid agency upon request; and

(iii) Advise the Secretary when there is no response to a request.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicare standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency will promptly furnish the information to the Secretary.

(2) Any disclosing entity that is not subject to periodic survey and certification must supply the information specified in paragraph (a) of this section to the Secretary before entering into a contract or agreement to participate in Medicare.

(3) Updated information must be furnished to the Secretary at intervals between recertifications or contract renewals, within 35 days of a written request.

(c) *Consequences of failure to disclose.* (1) The Secretary will not approve an agreement or contract with, or make a determination of eligibility for, any disclosing entity that fails to comply with paragraph (b) of this section.

(2) The Secretary will terminate any existing agreement or contract with, or withdraw a determination of eligibility for, any disclosing entity that fails to comply with paragraph (b) of this section.

(d) *Public disclosure.* Information furnished to the Secretary under the provisions of this section shall be subject to public disclosure as specified in 20 CFR Part 422.

Subpart D—Access to Books, Documents, and Records of Subcontractors

SOURCE: 47 FR 58267, Dec. 30, 1982, unless otherwise noted.

§ 420.300 Basis, purpose, and scope.

This subpart implements section 1861(v)(1)(I) of the Act, which requires, for Medicare payment under certain provider contracts, access by the Secretary, upon written request, and the Comptroller General, and their duly authorized representatives, to certain contracts for services and to books, documents, and records necessary to verify the costs of the services. The contracts affected are those between providers and their subcontractors, and between the subcontractors and organizations related to the subcontractor by control or common ownership. It also specifies the criteria by which HHS will determine whether to request access to books, documents, and records.

§ 420.301 Definitions.

For purposes of this subpart—

"Books, documents, and records" means all writings, recordings, transcriptions and tapes of any description necessary to verify the nature and extent of the costs of the services provided by the subcontractor.

"Common ownership" means that an individual or individuals possess significant ownership or equity in the subcontractor and the entity providing the services under the contract.

"Contract for services" means a contract through which a provider obtains the performance of an act or acts, as distinguished from supplies or equipment. It includes any contract for both goods and services to the extent the value or cost of the service component is $10,000 or more within a 12-month period.

"Control" means that an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions of policies of an organization.

"Provider" means a hospital, skilled nursing facility, home health agency, hospice or comprehensive outpatient rehabilitation facility, or a related organization (as defined in § 413.17 of this chapter) of any of these providers.

"Related to the subcontractor" means that the subcontractor is, to a significant extent, associated or affiliated with, owns, or is owned by, or has control of or is controlled by, the organization furnishing the services, facilities, or supplies.

"Subcontractor" means any entity, including an individual or individuals, that contracts with a provider to supply a service, either to the provider or directly to a beneficiary, for which Medicare reimburses the provider the cost of the service. This includes organizations related to the subcontractor that have a contract with the subcontractor for which the cost or value is $10,000 or more in a 12-month period.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984; 51 FR 34833, Sept. 30, 1986]

§ 420.302 Requirement for access clause in contracts.

(a) *Applicability.* This subpart applies to contracts—

(1) Between a provider and a subcontractor and, where subject to section 1861(v)(l)(I)(ii) of the Act, between a subcontractor and an organization related to the subcontractor;

(2) Entered into or renewed after December 5, 1980; and

(3) For services the cost or value of which is $10,000 or more over a 12-month period, including contracts for both goods and services in which the service component is worth $10,000 or more over a 12-month period.

(b) *Requirement.* Any contract meeting the conditions of paragraph (a) of this section must include a clause that allows the Comptroller General of the United States, HHS, and their duly authorized representatives access to the subcontractor's contract, books, documents, and records until the expiration of four years after the services are furnished under the contract or subcontract. The access must be provided for in accordance with the provisions of this subpart. The clause must also allow similar access by HHS, the Comptroller General, and their duly authorized representatives to contracts subject to section 1861(v)(l)(I)(ii) of the Act between a subcontractor and organizations related to the subcontractor and to books, documents, and records.

(c) *Prohibition against Medicare reimbursement.* If a contract subject to the requirements of this subpart does not contain the clause required by paragraph (b) of this section, HCFA will not reimburse the provider for the cost of the services furnished under the contract and will recoup any payments previously made for services under the contract. However, in order to avoid nonreimbursement or recoupment, providers will have until July 30, 1983, to amend those contracts entered into or renewed after December 5, 1980, and before January 31, 1983, that do not conform to the requirements of paragraph (b) of this section.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984]

§ 420.303 HHS criteria for requesting books, documents, and records.

HHS will generally request books, documents, and records from a subcontractor only if one of the following situations exists and the question cannot satisfactorily and efficiently be resolved without access to the books, documents, and records:

(a) HHS has reason to believe that the costs claimed for services of the subcontractor are excessive or inappropriate.

(b) There is insufficient information to judge the appropriateness of the costs.

(c) There is a written accusation with suitable evidence against the provider or subcontractor of kickbacks, bribes, rebates, or other illegal activities.

(d) There is evidence of a possible nondisclosure of the existence of a related organization.

§ 420.304 Procedures for obtaining access to books, documents, and records.

(a) *Contents of the request.* Requests for access will be in writing and contain the following elements:

(1) Reasonable identification of the books, documents, and records to which access is being requested.

(2) Identification of the contract or subcontract in which costs are being questioned as excessive or inappropriate.

(3) The reason that the appropriateness of the costs or value of the services of the subcontractor in question cannot be adequately or efficiently determined without access to the subcontractor's books and records.

(4) The authority in the statute and regulations for the access requested.

(5) To the extent possible, the identification of those individuals who will be visiting the subcontractor to obtain access to the books, documents, and records.

(6) The time and date of the scheduled visit.

(7) The name of the duly authorized representative of HHS to contact if there are any questions.

(b) *Subcontractor response to a request for access to books, documents, and records.* (1) The subcontractor will have 30 days from the date of a written request for access to books, documents, and records to make them available in accordance with the request.

(2) If the subcontractor believes the request is inadequate because it does not fully meet one or more of the required elements in paragraph (a) of this section, the subcontractor must advise the requesting organization of the additional information needed.

(i) The subcontractor must notify the requesting organization within 20 days of the date of the request that it was improperly completed.

(ii) The subcontractor must make the books, documents, and records available within 20 days after the date of the requesting organization's response.

(3) If the subcontractor believes, for good cause, that the requested books, documents, and records cannot be made available as requested with the 30-day period under paragraph (b)(1) of this section, the subcontractor may request an extension of time within which to comply with the request from the requesting organization. The requesting organization may, at its discretion, grant the request for an extension, in whole or in part, for good cause shown.

(4) The subcontractor must make the books, documents, and records available during its regular business hours for inspection, audit, and reproduction.

(5) If HHS asks the subcontractor to reproduce books, documents, and records, HHS will pay the reasonable cost of reproduction. However, if the subcontractor reproduces books, documents, and records as a means of making them available, the subcontractor must bear the cost of the reproduction and no Medicare reimbursement will be made for that purpose.

(6) HHS reserves the right to examine the originals of any requested contracts, books, documents, and records, if they exist.

(c) *Refusal by subcontractor to furnish access to records.* If HCFA determines that the books, documents, and records are necessary for the reimbursement determination and the subcontractor refuses to make them available, HHS may initiate legal action against the subcontractor.

PART 421—INTERMEDIARIES AND CARRIERS

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AUTHORITY: Secs. 1102, 1815, 1816, 1833, 1842, 1861(u), 1871, 1874, and 1875 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395h, 1395l, 1395u, 1395x(u), 1395hh, 1395kk, and 1395ll), and 42 U.S.C. 1395b-1.

SOURCE: 45 FR 42179, June 23, 1980, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to this part appear at 49 FR 3659, Jan. 30, 1984.

Subpart A—Scope, Definitions, and General Provisions

§ 421.1 Basis and scope.

(a) This part is based on sections 1815, 1816, 1842, and 1874 of the Social Security Act and 42 U.S.C. 1395b-1 (experimental authority).

(b) The provisions of this part apply to agreements with Part A (Hospital Insurance) intermediaries and contracts with Part B (Supplementary Medical Insurance) carriers. They also state that HCFA may perform certain functions directly or by contract. They specify criteria and standards to be used in selecting intermediaries and evaluating their performance, in assigning or reassigning a provider or providers to particular intermediaries, and in designating regional or national intermediaries for certain classes of providers. The provisions set forth the instances where there is the opportunity for a hearing for intermediaries and carriers affected by certain adverse actions. In some circumstances, the adversely affected intermediaries may request a judicial review of hearings decisions on—

(1) Assignment or reassignment of a provider or providers; or

(2) Designation of an intermediary or intermediaries to serve a class of providers.

[49 FR 3659, Jan. 30, 1984]

§ 421.3 Definitions.

"Intermediary" means an entity that has a contract with HCFA to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions. For purposes of designating regional or alternative regional intermediaries for home health agencies and of designating intermediaries for hospices under § 421.117 as well as for applying the performance criteria in § 421.120 and the statistical standards in § 421.122 and any adverse action resulting from such application, the term intermediary also means a Blue Cross Plan which has entered into a subcontract approved by HCFA with the Blue Cross and Blue Shield Association to perform intermediary functions.

[53 FR 17944, May 19, 1988]

§ 421.5 General provisions.

(a) *Competitive bidding not required for carriers.* HCFA may enter into contracts with carriers, or with intermediaries to act as carriers in certain circumstances, without regard to section 3709 of the U.S. Revised Statutes or any other provision of law that requires competitive bidding.

(b) *Indemnification of intermediaries and carriers.* Intermediaries and carriers act on behalf of HCFA in carrying out certain administrative responsibilities that the law imposes. Accordingly, their agreements and contracts contain clauses providing for indemnification with respect to actions taken on behalf of HCFA and HCFA is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* HCFA may contract with an intermediary to perform carrier functions with respect to services for which Part B payment is made to a provider.

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, HCFA has the authority not to renew an agreement or contract when its term expires.

(e) *Intermediary availability in an area.* For more effective and efficient administration of the program, HCFA retains the right to expand or diminish the geographical area in which an intermediary is available to serve providers.

Subpart B—Intermediaries

§ 421.100 Intermediary functions.

An agreement between HCFA and an intermediary shall provide for the performance of the following functions:

(a) *Coverage.* The intermediary must assure that it makes payments only for services that are—

(1) Furnished to Medicare beneficiaries;

(2) Covered under Medicare Part A or Part B; and

(3) Medically necessary. When a PRO has assumed review responsibility in accordance with the applicable provisions of Part 466 of this chapter, the PRO shall make final determinations of medical necessity which are binding for purposes of payment.

(b) *Fiscal management.* The intermediary must receive, disburse, and account for funds in making Medicare payments.

(c) *Provider audits.* The intermediary must audit the records of providers of services as necessary to assure proper payments.

(d) *Utilization patterns.* The intermediary must assist providers to—

(1) Develop procedures relating to utilization practices;

(2) Make studies of the effectiveness of those procedures and recommend methods to improve them;

(3) Evaluate the results of utilization review activity; and

(4) Assist in the application of safeguards against unnecessary utilization of services.

(e) *Resolution of cost report disputes.* The intermediary must establish and maintain procedures approved by HCFA to consider and resolve any disputes that may result from provider dissatisfaction with an intermediary's determinations concerning provider cost reports.

(f) *Review and reconsideration of determinations.* The intermediary must establish and maintain procedures approved by HCFA for the review and reconsideration of determinations that deny payments to an individual or to the provider who furnished services to the individual.

(g) *Information and reports.* The intermediary must furnish to HCFA any information and reports that HCFA requests in order to carry out its responsibilities in the administration of the Medicare program.

(h) *Other terms and conditions.* The intermediary must comply with all applicable laws and regulations and with any other terms and conditions included in its agreement.

(i) *Dual intermediary responsibilities.* With respect to the responsibility for service to provider-based HHAs and provider-based hospices, where the HHA or hospice and its parent provider will be served by different intermediaries under § 421.117 of this part, the designated regional intermediary will process bills, make coverage determinations and make payments to the HHAs and hospices. The intermediary serving the parent provider will perform all fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

[45 FR 42179, June 23, 1980, as amended at 48 FR 7178, Feb. 18, 1983; 49 FR 3659, Jan. 30, 1984; 51 FR 43198, Dec. 1, 1986; 53 FR 17944, May 19, 1988]

§ 421.103 Options available to providers and HCFA.

(a) Except for hospices (which are covered under § 421.117), a provider may elect to receive payment for covered services furnished to Medicare beneficiaries—

(1) Directly from HCFA (subject to the provisions of paragraph (b) of this section); or

(2) Through an intermediary, when both HCFA and the intermediary consent.

(b) Whenever HCFA determines it appropriate, it may contract with any organization (including an intermediary with which HCFA has previously entered into an agreement under § 421.105 and § 421.110 or designated as a regional or alternative regional intermediary under § 421.117) for the purposes of making payments to any provider that does not elect to receive payment from an intermediary.

[49 FR 3659, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984]

§ 421.104 Nominations for intermediary.

(a) *Nomination by groups or associations of providers.* (1) An association of providers, except for hospices, may nominate an organization or agency to serve as intermediary for its members.

(2) The nomination is not binding on any member of the association if it notifies HCFA of its nonconcurrence with the nomination.

(3) The nomination must be made in writing, to HCFA, and must—

(i) Identify the proposed intermediary by giving the complete name and address;

(ii) Include, or furnish as an attachment, the name, address, and bed capacity (or patient care capacity in the case of home health agencies) of each member of the association;

(iii) List the members that have concurred in the nomination of the proposed intermediary; and

(iv) Be signed by an authorized representative of the association.

(b) *Action by nonmembers or nonconcurring members.* Providers that nonconcur in their association's nomination, or are not members of an association, may—

(1) Form a group of 2 or more providers for the specific purpose of nominating an intermediary, in accordance with provisions of paragraph (a) of this section;

(2) Elect to receive payments from a fiscal intermediary with which HCFA already has an agreement, if HCFA and the intermediary agree to it (see § 421.106); or

(3) Elect to receive payment from HCFA as provided in § 421.103.

(c) HCFA is not required to enter into an agreement with a proposed intermediary solely because it has been nominated.

[45 FR 42179, June 23, 1980, as amended at 48 FR 56035, Dec. 16, 1983; 49 FR 3659, Jan. 30, 1984]

§ 421.105 Notification of action on nomination.

(a) HCFA will send, to each member of a nominating association or group, written notice of a decision to enter into or not enter into an agreement with the nominated organization or agency.

(b) Any member of a group or association having more than one nominated intermediary approved by HCFA to act on its behalf must withdraw its nomination from all but one or exercise the option provided in § 421.103(a), subject to § 421.103(b), to receive payment directly from HCFA.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§ 421.106 Change to another intermediary or to direct payment.

(a) Any provider may request a change of intermediary, or except for a hospice, that it be paid directly by HCFA, by—

(1) Giving HCFA written notice of its desire at least 120 days before the end of its current fiscal year; and

(2) Concurrently giving written notice to its intermediary.

(b) If HCFA finds the change is consistent with effective and efficient administration of the program and approves the request under paragraph (a) of this section, it will notify the provider, the outgoing intermediary, and the newly-elected intermediary (if any) that the change will be effective on the first day following the close of the fiscal year in which the request was filed.

[45 FR 42179, June 23, 1980, as amended at 49 FR 56036, Dec. 16, 1983; 49 FR 3660, Jan. 30, 1984]

§ 421.110 Requirements for approval of an agreement.

Before entering into or renewing an intermediary agreement, HCFA will—

(a) Determine that to do so is consistent with the effective and efficient administration of the Medicare program;

(b) Review the performance of the intermediary as measured by the criteria (§ 421.120) and standards (§ 421.122); and

(c) Determine that the intermediary or prospective intermediary—

(1) Is willing and able to assist providers in the application of safeguards against unnecessary utilization of services;

(2) Meets all solvency and financial responsibility requirements imposed by the statutes and regulatory authorities of the State or States in which it, or any subcontractor performing some or all of its functions, would serve;

(3) Has the overall resources and experience to administer its responsibilities under the Medicare program and has an existing operational, statistical, and recordkeeping capacity to carry out the additional program responsibilities it proposes to assume. HCFA will presume that an intermediary or prospective intermediary meets this requirement if it has at least 5 years experience in paying for or reimbursing the cost of health services;

(4) Will serve a sufficient number of providers to permit a finding of effective and efficient administration. Under this criterion no intermediary or prospective intermediary shall be found to be not efficient or effective solely on the grounds that it serves only providers located in a single State;

(5) Has acted in good faith to achieve effective cooperation with the providers it will service and with the physicians and medical societies in the area;

(6) Has established a record of integrity and satisfactory service to the public; and

(7) Has an affirmative equal employment opportunity program that complies with the fair employment provisions of the Civil Rights Act of 1964 and Executive Order 11246, as amended.

§ 421.112 Considerations relating to the effective and efficient administration of the program.

(a) In order to accomplish the most effective and efficient administration of the Medicare program, determinations may be made by the Secretary with respect to the termination of an intermediary agreement, or by HCFA with respect to the—

(1) Renewal of an intermediary agreement (§ 421.110);

(2) Assignment or reassignment of providers to an intermediary (§ 421.114); or

(3) Designation of a regional or national intermediary to serve a class of providers (§ 421.116).

(b) When taking the actions listed in paragraph (a), the Secretary or HCFA will consider the performance of the individual intermediary in its Medicare operations using the factors contained in the performance criteria (§ 421.120) and statistical standards (§ 421.122).

(c) In addition, when taking the actions listed in paragraph (a) of this section, the Secretary or HCFA may consider factors relating to—

(1) Consistency in the administration of program policy;

(2) Development of intermediary expertise in difficult areas of program administration;

(3) Individual capacity of available intermediaries to serve providers as it is affected by such considerations as—

(i) Program emphasis on the number or type of providers to be served; or

(ii) Changes in data processing technology;

(4) Overdependence of the program on the capacity of an intermediary to an extent that services could be interrupted;

(5) Economy in the delivery of intermediary services;

(6) Timeliness in the delivery of intermediary services;

(7) Duplication in the availability of intermediaries;

(8) Conflict of interest between an intermediary and provider; and

(9) Any additional pertinent factors.

§ 421.114 Assignment and reassignment of providers by HCFA.

HCFA may assign or reassign any provider to any intermediary if it determines that the assignment or reassignment will result in a more effective and efficient administration of the Medicare program. Before making this determination HCFA will consider—

(a) The preferences of the provider;

(b) The availability of an intermediary as specified in § 421.5(e); and

(c) Intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§ 421.116 Designation of national or regional intermediaries.

(a) After considering intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122, HCFA may designate a particular intermediary to serve a class of providers nationwide or in any geographic area it defines. HCFA may make this designation if it determines that the designation will result in a greater degree of effectiveness and efficiency in the administration of the Medicare program than could be achieved by an assignment of providers to an intermediary preferred by the providers.

(b) No designation may be made until the affected providers and intermediaries are given an explanation and the intermediaries are advised of their right to a hearing and judicial review as specified in § 421.128. This provision does not apply to experimental contracts awarded under § 421.118.

(c) To designate an intermediary, HCFA may establish classes of providers on the basis of—

(1) The type of provider, for example, hospital, skilled nursing facility, home health agency; or

(2) Common characteristics.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§ 421.117 Designation of regional and alternative designated regional intermediaries for home health agencies and hospices.

(a) This section is based on section 1816(e)(4) of the Social Security Act, which requires the Secretary to designate regional intermediaries for home health agencies (HHAs) other than hospital-based HHAs but permits him or her to designate regional intermediaries for hospital-based HHAs only if the designation meets promulgated criteria concerning administrative efficiency and effectiveness; on section 1816(e)(5) of the Social Security Act, which requires the Secretary to designate intermediaries for hospices; and on section 1874 of the Act, which permits HCFA to contract with any organization for the purpose of making payments to any provider that elects to receive payment directly from HCFA.

(b) HCFA applies the following criteria to determine whether the assignment of hospital-based HHAs to designated regional intermediaries will result in the more effective and efficient administration of the Medicare program:

(1) Uniform interpretation of Medicare rules;

(2) Expertise in bill processing;

(3) Control of administrative costs;

(4) Ease of communication of program policy and issues to affected providers;

(5) Ease of data collection;

(6) Ease of HCFA's monitoring of intermediary performance; and

(7) Other criteria as the Secretary believes to be pertinent.

(c) Except as provided in paragraphs (e), (f), and (g) of this section, an HHA must receive payment through a regional intermediary designated by HCFA.

(d) Except as provided in paragraphs (f) through (h) of this section, a hospice must receive payment for covered services furnished to Medicare beneficiaries through an intermediary designated by HCFA.

(e) An HHA chain not desiring to receive payment from designated regional intermediaries may request service by one lead intermediary with the assistance of a local designated regional intermediary. Alternatively, the chain may request to be serviced by a single intermediary. A lead, local, or a single intermediary must be an organization that is a designated regional intermediary. Any request made under this paragraph is evaluated by HCFA in accordance with the criteria contained at § 421.106 of this subpart.

(f) An HHA or hospice not wishing to receive payment from a regional intermediary designated under paragraph (c) or (d) of this section may submit a request to the HCFA Regional Office to receive payment through an alternative regional intermediary designated by HCFA.

(g) Except as provided in paragraph (h) of this section, any request that an HHA or hospice may make to change from a designated regional intermediary to an alternative designated regional intermediary, in accordance with paragraph (f) of this section, is evaluated by HCFA in accordance with the criteria set forth at § 421.106(b) of this subpart and must be filed within the timeframe established at § 421.106(a) of this subpart.

(h) *Exception:* An HHA or a hospice that, as of June 20, 1988 is receiving payment from a designated regional intermediary may, without regard to the limitations contained in § 421.106 of this subpart, continue to receive payment from that intermediary. It may do so even if that intermediary is not the designated regional intermediary or the alternative designated regional intermediary for the particular State in which the HHA or hospice is located.

[53 FR 17944, May 19, 1988]

§ 421.118 Awarding of experimental contracts.

Notwithstanding the provisions of §§ 421.103 and 421.104, HCFA may award a fixed price or performance incentive contract under the experimental authority contained in 42 U.S.C. 1395b-1 for performance of any of the functions specified in § 421.100. Action taken by HCFA under this paragraph is not subject to—

(a) The administrative and judicial review which would otherwise be available under § 421.128; or

(b) Performance criteria and statistical standards review as provided for in §§ 421.120 and 421.122.

§ 421.120 Performance criteria.

(a) *Application of performance criteria.* As part of the intermediary evalutions authorized by section 1816(f) of the Act, HCFA periodically assesses the performance of intermediaries in their Medicare operations using performance criteria. The criteria measure and evaluate intermediary performance of functional responsibilities such as—

(1) Correct coverage and payment determinations;

(2) Responsiveness to beneficiary concerns; and

(3) Proper management of administrative funds.

(b) *Basis for criteria.* HCFA will base the performance criteria on—

(1) Nationwide intermediary experience;

(2) Changes in intermediary operations due to fiscal constraints; and

(3) HFCA's objectives in achieving better performance.

(c) *Publication of criteria.* The development and revision of criteria for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, HCFA will publish the performance criteria as a notice in the FEDERAL REGISTER.

[48 FR 7178, Feb. 18, 1983]

§ 421.122 Statistical standards.

(a) *Development of standards.* In addition to the performance criteria (§ 421.120), HCFA will develop statistical standards, for use in evaluating intermediary performance, based on application of acceptable statistical measures of variation to nationwide intermediary experience during a base period. HCFA will adjust those standards dealing with administrative cost to reflect both the estimated effect of inflation and increased intermediary productvity.

(b) *Factors beyond intermediary's control.* To identify measurable factors that significantly affect an intermediary's performance, but that are not within the intermediary's control, HCFA will—

(1) Study the performance of intermediaries during the base period using acceptable statistical approaches (for example, multiple regression analysis); and

(2) Select the noncontrollable factors to be used in adjusting performance standards.

(c) *Publication of standards.* The development and revision of standards for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, HCFA will publish the statistical standards as part of the FEDERAL REGISTER notice describing the performance criteria issued under § 421.120(c).

[48 FR 7179, Feb. 18, 1983]

§ 421.124 Intermediary's failure to meet criteria or standards.

Failure by an intermediary to meet, or demonstrate the capacity to meet, the criteria or standards specified in §§ 421.120 and 421.122 may be grounds for adverse action by the Secretary or by HCFA, such as reassigning providers, offering a short-term agreement, or termination. If an intermediary meets all criteria and standards in its overall performance, but does not meet them with respect to a specific provider or class of providers, HCFA may reassign that provider or class of providers to another intermediary in accordance with § 421.114.

§ 421.126 Termination of agreements.

(a) *Termination by intermediary.* An intermediary may terminate its agreement at any time by—

(1) Giving written notice of its intention to HCFA and to the providers it services at least 180 days before its intended termination date; and

(2) Giving public notice of its intention by publishing a statement of the effective date of termination at least 60 days before that date. Publication must be in a newspaper of general circulation in each community served by the intermediary.

(b) *Termination by the Secretary, and right of appeal.* (1) The Secretary may terminate an agreement if—

(i) The intermediary fails to comply with the requirements of this subpart;

(ii) The intermediary fails to meet the criteria or standards specified in §§ 421.120 and 421.122; or

(iii) HCFA has reassigned, under § 421.114 or § 421.116, all of the providers assigned to the intermediary.

(2) If the Secretary decides to terminate an agreement, he or she will offer the intermediary an opportunity for a hearing, in accordance with § 421.128.

(3) If the intermediary does not request a hearing, or if the hearing decision affirms the Secretary's decision, the Secretary will provide reasonable notice of the effective date of termination to—

(i) The intermediary;

(ii) The providers served by the intermediary; and

(iii) The general public.

(4) The providers served by the intermediary will be given the opportunity to nominate another intermediary, in accordance with § 421.104.

§ 421.128 Intermediary's opportunity for hearing and right to judicial review.

(a) *Basis for appeal.* An intermediary adversely affected by any of the following actions shall be granted an opportunity for a hearing:

(1) Assignment or reassignment of providers to another intermediary.

(2) Designation of a national or regional intermediary to serve a class of providers.

(3) Termination of the agreement.

(b) *Request for hearing.* The intermediary shall file the request with HCFA within 20 days from the date on the notice of intended action.

(c) *Hearing procedures.* The hearing officer shall be a representative of the Secretary and not otherwise a party to the initial administrative decision. The intermediary may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings at the hearing will be made and transcribed.

(d) *Judicial review.* An adverse hearing decision concerning action under paragraph (a)(1) or (a)(2) of this section is subject to judicial review in accordance with 5 U.S.C. chapter 7.

(e) As specified in § 421.118, contracts awarded under the experimental authority of HCFA are not subject to the provisions of this section.

(f) *Exception.* An intermediary adversely affected by the designation of a regional intermediary or an alternative regional intermediary for HHAs, or an intermediary for hospices, under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

[45 FR 42179, June 23, 1980, as amended at 47 FR 38540, Sept. 1, 1982; 49 FR 3660, Jan. 30, 1984 53 FR 17945, May 19, 1988]

Subpart C—Carriers

§ 421.200 Carrier functions.

A contract between HCFA and a carrier shall provide for the performance of the following functions:

(a) *Coverage.* (1) The carrier must assure that payment is made only for services that are—

(i) Rendered to Medicare beneficiaries;

(ii) Covered under Medicare Part B; and

(iii) Medically necessary. When a PRO has assumed review responsibility in accordance with the applicable provisions of Part 466 of this chapter, the PRO shall make final determinations of medical necessity which are binding for purposes of payment.

(2) If it determines that the services were not medically necessary or the claim does not properly reflect the kind and amount of services furnished, the carrier must take appropriate action to reject or adjust the claim.

(b) *Payment on a cost basis.* If payment is on a cost basis, the carrier must assure that payments are based on reasonable costs, as determined under Part 413 of this chapter.

(c) *Payment on a charge basis.* If payment is on a charge basis, under Part 405, Subpart E of this chapter, the carrier must ensure that—

(1) Charges are reasonable and not higher than the charge for a comparable service furnished under comparable circumstances to the carrier's policy holders and subscribers; and

(2) The payment is based on one of the following—

(i) An itemized bill.

(ii) An assignment under the terms of which the reasonable charge is the full charge for the service, as specified in § 424.55 of this chapter.

(iii) If the beneficiary has died, the procedures set forth in §§ 424.62 and 424.64 of this chapter.

(d) *Fiscal management.* The carrier must receive, disburse, and account for funds in making payments under Medicare.

(e) *Provider audits.* The carrier must audit the records of providers to whom it makes Medicare Part B payments to assure that payments are made properly.

(f) *Utilization patterns.* (1) The carrier must have methods and procedures for identifying utilization patterns that deviate from professionally established norms and bring the deviant patterns to the attention of appropriate professional groups.

(2) The carrier must assist providers and other persons who furnish Medicare Part B services to—

(i) Develop procedures relating to utilization practices;

(ii) Make studies of the effectiveness of those procedures and devise methods to improve them;

(iii) Apply safeguards against unnecessary utilization of services; and

(iv) Develop procedures for utilization review, and establish groups to perform such reviews of providers to whom it makes Medicare Part B payments.

(g) *Information and reports.* The carrier must furnish to HCFA any information and reports that HCFA requests in order to carry out HCFA's responsibilities in the administration of the Medicare program. The carrier must be responsive to requests for information from the public.

(h) *Maintenance and availability of records.* The carrier must maintain and make available to HCFA the records necessary for verification of payments and for other related purposes.

(i) *Hearings to Part B beneficiaries.* (1) The carrier must provide an opportunity for a fair hearing if it denies the beneficiary's request for payment, does not act upon the request with reasonable promptness, or pays less than the amount claimed.

(2) The hearing procedures must be in accordance with Part 405, Subpart H, of this chapter (Review and Hearing Under the Supplementary Medical Insurance Program).

(j) *Other terms and conditions.* The carrier must comply with any other terms and conditions included in its contract.

[45 FR 42183, Jun. 23, 1980; 45 FR 64913, Oct. 1, 1980, as amended at 49 FR 3660, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984; 51 FR 34833, Sept. 30, 1986; 51 FR 41350, Nov. 14, 1986; 51 FR 43198, Dec. 1, 1986; 52 FR 4499, Feb. 12, 1987; 53 FR 6648, Mar. 2, 1988]

§ 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, HCFA will determine that the carrier—

(a) Has the capacity to perform its contractual responsibilities effectively and efficiently;

(b) Has the financial responsibility and legal authority necessary to carry out its responsibilities; and

(c) Will be able to meet any other requirements HCFA considers pertinent.

§ 421.204 Provision for automatic renewal of contracts.

Contracts under this subpart may contain an automatic renewal provision, continuing the contract from term to term unless either party gives at least 90 days notice of its intention not to renew it at the end of the current term.

[48 FR 30119, June 30, 1983]

§ 421.205 Termination by the Secretary.

(a) *Cause for termination.* The Secretary may terminate a contract with a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its function in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(b) *Notice and opportunity for hearing.* Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date on the notice of intent to terminate.

(c) *Hearing procedures.* The hearing procedures will be those specified in § 421.128(c).

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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Subpart M—Replacement and Reclamation of Medicare Payments

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AUTHORITY: Secs. 216(j), 1102, 1814, 1815(c), 1835, 1842(b), 1861, 1866(d), 1870 (e) and (f), 1871 and 1872 of the Social Security Act (42 U.S.C. 416(j), 1302, 1395f, 1395g, 1395n, 1395u, 1395x, 1395cc, 1395gg, 1395hh and 1395ii).

SOURCE: 53 FR 6634, Mar. 2, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 424.1 Basis and scope.

(a) *Statutory basis.* This part implements the provisions of sections 1814, 1835, 1842(b)(3), and 1870 (e) and (f) of the Act, which establish conditions for and limitations on Medicare payments, and sections 1815(c) and 1842(b)(6), which prohibit assignment or reassignment of the right to those payments.

(b) *Scope.* This part sets forth certain specific conditions and limitations applicable to Medicare payments and cites other conditions and limitations set forth elsewhere in this chapter. This Subpart A provides a general overview. Other subparts deal specifically with—

(1) The requirement that a physician certify the need for services and establish a plan of treatment (Subpart B);

(2) The procedures and time limits for filing claims (Subpart C);

(3) The individuals or entities to whom payment may be made (Subparts D and E);

(4) The limitations on assignment and reassignment of claims (Subpart F);

(5) Special requirements that apply to services furnished by nonparticipat-

ing U.S. hospitals and foreign hospitals (Subparts G and H); and

(6) The replacement and reclamation of Medicare payment checks (Subpart M).

Except for § 424.40(c)(3), this part does not deal with the conditions for payment of rural health clinic (RHC) services or ambulatory surgical center (ASC) services. Those conditions are set forth in Part 405, Subpart X, and Part 481 Subpart A of this chapter for RHC services; and in Part 416 of this chapter, for ASC services.

§ 424.3 Definitions.

As used in this part, unless the context indicates otherwise—

"Nonparticipating hospital" means a hospital that does not have in effect a provider agreement to participate in Medicare.

"Participating hospital" means a hospital that has in effect a provider agreement to participate in Medicare.

§ 424.5 Basic conditions.

(a) As a basis for Medicare payment, the following conditions must be met:

(1) *Types of services.* The services must be—

(i) Covered services, as specified in Part 409 or Part 410 of this chapter; or

(ii) Services excluded from coverage as custodial care or services not reasonable and necessary, but reimbursable in accordance with §§ 405.332 through 405.334 of this chapter, pertaining to limitation of liability.

(2) *Sources of services.* The services must have been furnished by a provider, nonparticipating hospital, or supplier that was, at the time it furnished the services, qualified to have payment made for them.

(3) *Recipient of services.* Except as provided in § 409.68 of this chapter, the services must have been furnished while the individual was eligible to have payment made for them. (Section 409.68 provides for payment of inpatient hospital services furnished before the hospital is notified that the beneficiary has exhausted the Medicare benefits available for the current benefit period.)

(4) *Certification of need for services.* When required, the provider must obtain physician certification and recertification of the need for the services in accordance with Subpart B of this part.

(5) *Claim for payment.* The provider, supplier, or beneficiary, as appropriate, must file a claim that includes or makes reference to a request for payment, in accordance with Subpart C of this part.

(6) *Sufficient information.* The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.

(b) Additional conditions applicable in certain circumstances or to certain services are set forth in other sections of this part.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.7 General limitations.

(a) *Utilization review finding on medical necessity.* When a PRO or a UR committee notifies a hospital or SNF of its finding that further services are not medically necessary, the following rules apply:

(1) *Hospitals subject to PPS.* Payment may not be made for inpatient hospital services furnished by a PPS hospital after the second day after the day on which the hospital received the notice.

(2) *Hospitals not subject to PPS and SNFs*—(i) *Basic rule.* Except as provided in paragraph (a)(2)(ii) of this section, payment may not be made for inpatient hospital services or posthospital SNF care furnished after the day on which the hospital or SNF received the notice.

(ii) *Exception.* Payment may be made for 1 or 2 additional days if the PRO or UR committee approves them as necessary for planning for post-discharge care.

(b) *Failure to make timely utilization review.* Payment may not be made for inpatient hospital services or posthospital SNF care furnished, after the 20th consecutive day of a stay, to an individual who is admitted to the hospital or SNF after HCFA has determined that the hospital or SNF has failed to make timely utilization review in long stay cases. (This provision does not apply to a hospital or SNF for which a PRO has assumed binding review.)

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart B—Physician Certification and Plan of Treatment Requirements

§ 424.10 Purpose and scope.

(a) *Purpose.* The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of stay. Accordingly, sections 1814(a)(2) and 1835(a)(2) of the Act establish as a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services.

(b) *Scope.* This subpart sets forth the content and timing requirements for certification and recertification of need for most services and the plan of treatment requirements for home health services, outpatient physical therapy and speech pathology services, home dialysis support services, and comprehensive outpatient rehabilitation facility (CORF) services.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.11 General procedures.

(a) *Responsibility of the provider.* The provider must—

(1) Obtain the required certification and recertification statements;

(2) Keep them on file for verification by the intermediary, if necessary; and

(3) Certify, on the appropriate billing form, that the statements have been obtained and are on file.

(b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that a physician signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification.

(c) *Required information.* The succeeding sections of this subpart set forth specific information required for different types of services. If that information is contained in other provider records, such as physicians' progress notes, it need not be repeated. It will suffice for the statement to indicate where the information is to be found.

(d) *Timeliness.* (1) The succeeding sections of this subpart also specify the time frames for certifications and for initial and subsequent recertifications.

(2) A hospital or SNF may provide for obtaining a certification or recertification earlier than required by these regulations, or vary the time frame (within the prescribed outer limits) for different diagnostic or clinical categories.

(3) Delayed certification and recertification statements are acceptable when there is a legitimate reason for delay. (For instance, the patient was unaware of his or her entitlement when he or she was treated.) Delayed certification and recertification statements must include an explanation of the reason for the delay.

(4) A delayed certification may be included with one or more recertifications on a single signed statement.

(e) *Limitation on authorization to sign statements.* A physician certification or recertification statement may be signed only by one of the following:

(1) A physician who is a doctor of medicine or osteopathy.

(2) A dentist in the circumstances specified in § 424.13(c).

(3) A doctor of podiatric medicine if his or her certification is consistent with—

(i) The policy of the institution or agency to which he or she provides the certification; and

(ii) The functions he or she is authorized to perform under State law.

§ 424.13 Requirements for inpatient services of hospitals other than psychiatric hospitals.

(a) *Content of certification and recertification.* Medicare Part A pays for inpatient hospital services of hospitals other than psychiatric hospitals only if a physician certifies and recertifies the following:

(1) The reasons for either—

(i) Continued hospitalization of the patient for medical treatment or medically required inpatient diagnostic study; or

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in Subpart F of Part 412 of this chapter).

(2) The estimated time the patient will need to remain in the hospital.

(3) The plans for posthospital care, if appropriate.

(b) *Certification of need for hospitalization when a SNF bed is not available.* (1) A physician may certify or recertify need for continued hospitalization if the physician finds that the patient could receive proper treatment in a SNF but no bed is available in a participating SNF.

(2) If this is the basis for the physician's certification or recertification, the required statement must so indicate; and the physician is expected to continue efforts to place the patient in a participating SNF as soon as a bed becomes available.

(c) *Signatures.* (1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, certifications and recertifications must be signed by the physician responsible for the case, or by another physician who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

(2) *Exception.* If the intermediary requests certification of the need to admit a patient in connection with dental procedures, because his or her underlying medical condition and clinical status or the severity of the dental procedures require hospitalization, that certification may be signed by the dentist caring for the patient.

(d) *Timing of certifications and recertifications: Cases not subject to the prospective payment system* (PPS). (1) For cases that are not subject to PPS, certification is required no later than as of the 12th day of hospitalization. A hospital may, at its option, provide for the certification to be made earlier, or it may vary the timing of the certification within the 12-day period by diagnostic or clinical categories. (2) The first recertification is required no later than as of the 18th day of hospitalization. (3) Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Timing of certification and recertification: Cases subject to PPS.* For cases subject to PPS, certification is required as follows:

(1) For day-outlier cases, certification is required no later than one day after the hospital reasonably assumes that the case meets the outlier criteria, established in accordance with § 412.80(a)(1)(i) of this chapter, or no later than 20 days into the hospital stay, whichever is earlier. The first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses) but not less frequently than every 30 days.

(2) For cost-outlier cases, certification is required no later than the date on which the hospital requests cost outlier payment or 20 days into the hospital stay, whichever is earlier. If possible, certification must be made before the hospital incurs costs for which it will seek cost outlier payment. In cost outlier cases, the first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses).

(f) *Recertification requirement fulfilled by utilization review.* (1) At the hospital's option, extended stay review by its UR committee may take the place of the second and subsequent physician recertifications required for cases not subject to PPS and for PPS day-outlier cases.

(2) A utilization review that is used to fulfill the recertification requirement is considered timely if performed no later than the seventh day after the day the physician recertification would have been required. The next physician recertification would need

to be made no later than the 30th day following such review; if review by the UR committee took the place of this physician recertification, the review could be performed as late as the seventh day following the 30th day.

(g) *Description of procedures.* The hospital must have available on file a written description that specifies the time schedule for certifications and recertifications, and indicates whether utilization review of long-stay cases fulfills the requirement for second and subsequent recertifications of all cases not subject to PPS and of PPS day outlier cases.

§ 424.14 Requirements for inpatient services of psychiatric hospitals.

(a) *Content of certification and recertification: General considerations.* The content requirements differ from those for other hospitals because the care furnished in psychiatric hospitals is often purely custodial and thus not covered under Medicare. The purpose of the statements, therefore, is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage. Accordingly, Medicare Part A pays for inpatient care in a psychiatric hospital only if a physician certifies and recertifies the need for services consistent with the content of paragraphs (b) or (c) of this section, as appropriate.

(b) *Content of certification.* Inpatient psychiatric services were required—

(1) For treatment that could reasonably be expected to improve the patient's condition; or

(2) For diagnostic study.

(c) *Content of recertification.* (1) Inpatient services furnished since the previous certification or recertification were, and continue to be, required—

(i) For treatment that could reasonably be expected to improve the patient's condition; or

(ii) For diagnostic study; and

(2) The hospital records show that the services furnished were—

(i) Intensive treatment services;

(ii) Admission and related services necessary for diagnostic study; or

(iii) Equivalent services.

(d) *Timing of certification and recertification.* (1) Certification is required at the time of admission or as soon thereafter as is reasonable and practicable.

(2) The first recertification is required as of the 18th day of hospitalization. Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Other requirements.* Psychiatric hospitals must also meet the requirements set forth in § 424.13 (b), (c), (f), and (g).

§ 424.16 Timing of certification for individual admitted to a hospital before entitlement to Medicare benefits.

(a) *Basic rule.* If an indivdual is admitted to a hospital before becoming entitled to Medicare benefits (for instance, before attaining age 65), the day of entitlement (instead of the day of admission) is the starting point for the time limits specified in § 424.13(e) for certification and recertification.

(b) *Example.* (*Hospital that is not a psychiatric hospital and is not subject to PPS*). For a patient who is admitted on August 15 and becomes entitled on September 1—

(1) The certification is required no later than September 12;

(2) The first recertification is required no later than September 18; and

(3) Subsequent recertifications are required at least every 30 days after September 18.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.20 Requirements for posthospital SNF care.

Medicare Part A pays for posthospital SNF care furnished by a SNF or a hospital with a swing-bed approval only if a physician certifies and recertifies the need for services consistent with the content of paragraph (a) or (c) of this section, as appropriate.

(a) *Content of certification.* (1) Posthospital SNF care is or was required because the individual needs or needed on a daily basis skilled nursing care (furnished directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in a SNF or a swing-bed hospital on an inpatient basis; and

(2) The SNF care is or was needed for a condition for which the individual received inpatient care in a participating hospital or a qualified hospital, as defined in § 409.3 of this chapter.

(b) *Timing of certification.* The certification must be obtained at the time of admission or as soon thereafter as is reasonable and practicable.

(c) *Content of recertifications.* (1) The reasons for the continued need for posthospital SNF care;

(2) The estimated time the individual will need to remain in the SNF;

(3) Plans for home care, if any; and

(4) If appropriate, the fact that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he or she had received inpatient hospital services.

(d) *Timing of recertifications.* (1) The first recertification is required no later than the 14th day of posthospital SNF care.

(2) Subsequent recertifications are required at least every 30 days after the first recertification.

(e) *Signature.* Certification and recertification statements may be signed by the physician responsible for the case or, with his or her authorization, by a physician on the SNF staff or a physician who is available in case of an emergency and has knowledge of the case.

(f) *Recertification requirement fulfilled by utilization review.* A SNF may substitute utilization review of extended stay cases for the second and subsequent recertifications, if it includes this procedure in its utilization review plan.

(g) *Description of procedures.* The SNF must have available on file a written description that specifies the certification and recertification time schedule and indicates whether utilization review is used as an alternative to the second and subsequent recertifications.

§ 424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) *Certification*—

(1) *Content of certification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify as follows:

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy.

(ii) Home health services were required because the individual was confined to the home except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (Performance of plan of treatment functions by a doctor of podiatric medicine is subject to limitations specified in § 409.42(d) of this chapter.)

(iv) The services were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.[1] (Care by a doctor of podiatric medicine fulfills this requirement only if the conditions of § 409.42(b)(2) of this chapter are met.)

(2) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of treatment is established or as soon thereafter as possible and must be signed by the physician who establishes the plan.

(b) *Recertification*—(1) *Timing and signature of recertification.* Recertification is required at least every 2 months, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the plan.

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[1] As a condition of Medicare Part A payment for home health services furnished before July 1981, the physician was also required to certify that the services were needed for a condition for which the individual had received inpatient hospital or SNF services.

(2) *Content and basis of recertification.* The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical or speech therapy.

(c) *Certification by a doctor of podiatric medicine.* After December 31, 1980, for purposes of certifying and recertifying need for home health services, the term "physician" may include a doctor of podiatric medicine if—

(1) The beneficiary needs the services because of a podiatric condition which that doctor is legally authorized to treat; and

(2) Performance of the certification function by a doctor of podiatric medicine is consistent with the HHA's policy.

(d) *Limitations on the performance of certification and plan of treatment functions*—(1) *Basic rule.* Beginning November 26, 1982, and except as provided in paragraph (e) of this section, need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a significant ownership interest in, or a significant financial or contractual relationship with, that HHA.

(2) *Significant ownership interest.* A physician is considered to have a significant ownership interest in an HHA if he or she—

(i) Has a direct or indirect ownership interest of 5 percent or more in the capital, the stock, or the profits of the home health agency; or

(ii) Has an ownership interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation that is secured by the agency, if that interest equals 5 percent or more of the agency's assets.

(3) *Significant financial or contractual relationship.* Beginning November 26, 1982, a physician is considered to have a significant financial or contractual relationship with an HHA if he or she—

(i) Receives any compensation as an officer or director of the HHA; or

(ii) Has direct or indirect business transactions with the HHA that, in any fiscal year, amount to more than $25,000 or 5 percent of the agency's total operating expenses, whichever is less. Business transactions means contracts, agreements, purchase orders, or leases to obtain services, supplies, equipment, and space and, after August 29, 1986, salaried employment.

(4) *Exemption of uncompensated officer or director.* A physician who serves as an uncompensated officer or director of an HHA is not precluded from performing physician certification and plan of treatment functions for that HHA.

(e) *Exceptions to limitations.*—(1) *Exceptions for governmental entities.* The limitations of paragraph (d) of this section do not apply to an HHA that is operated by a Federal, State, or local governmental authority.

(2) *Exception for sole community HHAs.* The limitations of paragraph (d) of this section do not apply on or after the date on which the HHA is classified as a sole community HHA in accordance with paragraphs (f) and (g) of this section.

(f) *Procedures for classification as a sole community HHA.* (1) The HHA must submit to its intermediary a request for classification, showing that it meets the conditions of paragraph (g) of this section.

(2) The intermediary reviews the request and sends the request, with its recommendations, to HCFA.

(3) HCFA reviews the request and the intermediary's recommendation and forwards its approval or disapproval to the intermediary

(4) An approved classification as sole community HHA remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved.

(g) *Basis for classification as a sole community HHA.* HCFA approves a classification as a sole community HHA only if the HHA designates a particular area and shows that no other HHA provides services within that area.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.24 Requirements for medical and other health services under Medicare Part B.

(a) *Exempted services.* Certification is not required for—

(1) Hospital services and supplies, including drugs and biologicals that cannot be self-administered, incident to physicians' services furnished to outpatients;

(2) Outpatient hospital diagnostic services, including necessary drugs and biologicals, ordinarily furnished or arranged for by a hospital for the purpose of diagnostic study; or

(3) Outpatient physical therapy services furnished in the patient's home or in the practitioner's office, by or under the direct supervision of a qualified physical therapist in independent practice. (See § 424.25 for plan of treatment requirements applicable to these services.)

(b) *General rule.* Medicare Part B pays for medical and other health services not exempted under paragraph (a) of this section only if a physician certifies the content specified in paragraph (c)(1), (c)(4), (d), or (e)(1) of this section, as appropriate.

(c) *Outpatient physical therapy and speech pathology services.*—(1) *Content of certification.* (i) The individual needs, or needed, physical therapy or speech pathology services.

(ii) The services were furnished while the individual was under the care of a physician. (For physical therapy services furnished after July 17, 1984, the physician may be a doctor of podiatric medicine, provided the services are consistent with the functions he or she is authorized to perform under State law and, if the services are furnished in an institution or agency, with the policy of that institution or agency.)

(iii) The services were furnished under a plan of treatment that meets the requirements of § 424.25.

(2) *Timing.* The certification statement must be obtained at the time the plan of treatment is established, or as soon thereafter as possible.

(3) *Signature.* (i) If the plan of treatment is established by a physician, the certification must be signed by that physician.

(ii) If the plan of treatment is established by a physical therapist or speech pathologist, the certification must be signed by a physician who has knowledge of the case.

(4) *Recertification*—(i) *Timing.* Recertification statements are required at least every 30 days and must be signed by the physician who reviews the plan of treatment.

(ii) *Content.* The continuing need for physical therapy or speech pathology services and an estimate of how much longer the services will be needed.

(d) *Home dialysis support services: Content of certification.* A physician must certify that the services are furnished in accordance with a written plan of treatment established and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition.

(e) *All other covered medical and other health services furnished by providers.*—(1) *Content of certification.* The services were medically necessary.

(2) *Signature.* The certificate must be signed by a physician who has knowledge of the case.

(3) *Timing.* The physician may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or at the end of a series of visits.

(4) *Recertification.* Recertification of continued need for services is not required.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.25 Plan of treatment requirements for outpatient physical therapy and speech pathology services.

(a) *Basic requirement.* Outpatient physical therapy services (including services furnished by a qualified physical therapist in independent practice), and outpatient speech pathology services must be furnished under a written plan of treatment that meets the requirements of paragraphs (b) through (e) of this section.

(b) *Establishment of the plan.* The plan is established before treatment is begun by one of the following: [1]

(1) A physician.

(2) A physical therapist who will furnish the physical therapy services.

(3) A speech pathologist who will furnish the speech pathology services.

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy or speech pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan—

(1) Are made in writing and signed by one of the following:

(i) The physician or the physical therapist or speech pathologist who furnishes the services.

(ii) A registered professional nurse or a staff physician, in accordance with oral orders from the physician, physical therapist, or speech pathologist who furnishes the services.

(2) The changes are incorporated in the plan immediately.

(e) *Review of the plan.* (1) The physician reviews the plan as often as the individual's condition requires, but at least as often as the physician recertifies the continued need for services.

(2) Each review is dated and signed by the physician who performs it.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.27 Requirements for comprehensive outpatient rehabilitation facility (CORF) services.

Medicare Part B pays for CORF services only if a physician certifies, and the facility physician recertifies, the content specified in paragraphs (a) and (b)(2) of this section, as appropriate.

(a) *Certification: Content.* (1) The services were required because the individual needed skilled rehabilitation services;

(2) The services were furnished while the individual was under the care of a physician; and

(3) A written plan of treatment has been established and is reviewed periodically by a physician.

(b) *Recertification*—(1) *Timing.* Recertification is required at least every 60 days, based on review by a facility physician who, when appropriate, consults with the professional personnel who furnish the services.

(2) *Content.* (i) The plan is being followed;

(ii) The patient is making progress in attaining the rehabilitation goals; and

(iii) The treatment is not having any harmful effect on the patient.

Subpart C—Claims for Payment

§ 424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by a health maintenance organization (HMO), a competitive medical plan (CMP), or a health care prepayment plan (HCPP). Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in Subpart E of this part.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.32 Basic requirements for all claims.

(a) All claims must be—

(1) Filed with the appropriate intermediary or carrier on a form prescribed by HCFA and in accordance with HCFA instructions;

(2) Signed by the beneficiary or the beneficiary's representative (in accordance with § 424.36(b)) unless the beneficiary has died; and

(3) Filed within the time limits specified in § 424.44.

(b) The prescribed forms for claims are the following:

HCFA-1450—Uniform Institutional Provider Bill. (This form is for institutional provider billing for Medicare inpatient, outpatient and home health services.)

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[1] Before January 1981, only a physician could establish a plan of treatment for physical therapy or speech pathology services. Speech pathologists were authorized to establish a plan effective January 1, 1981; physical therapists, effective July 18, 1984.

HCFA-1490S—Request for Medicare payment. (For use by a patient to request payment for medical expenses.)

HCFA-1490U—Request for Medicare Payment by Organization. (For use by an organization requesting payment for medical services.)

HCFA-1491—Request for Medicare Payment-Ambulance. (For use by an organization requesting payment for ambulance services.)

HCFA-1500—Health Insurance Claim Form. (For use by physicians and other suppliers to request payment for medical services.)

HCFA-1660—Request for Information-Medicare Payment for Services to a Patient now Deceased. (For use in requesting amounts payable under title XVIII to a deceased beneficiary.)

(c) *Where claims forms are available.* Excluding forms HCFA-1450 and HCFA-1500, all claims forms prescribed for use in the Medicare program are distributed free-of-charge to the public, institutions, or organizations. The HCFA-1450 and HCFA-1500 may be obtained only by commercial purchase. All other claims forms can be obtained upon request from HCFA or any Social Security branch or district office, or from Medicare intermediaries or carriers. The HCFA-1490S is also available at local Social Security Offices.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.33 Additional requirements: Claims for services of providers and claims by suppliers and nonparticipating hospitals.

All claims for services of providers and all claims by suppliers and nonparticipating hospitals must be—

(a) Filed by the provider, supplier, or hospital; and

(b) Signed by the provider, supplier, or hospital unless HCFA instructions waive this requirement.

§ 424.34 Additional requirements: Beneficiary's claim for direct payment.

(a) *Basic rule.* A beneficiary's claim for direct payment for services furnished by a supplier, or by a nonparticipating hospital that has not elected to claim payment for emergency services, must include an itemized bill or a "report of services", as specified in paragraphs (b) and (c) of this section.

(b) *Itemized bill from the hospital or supplier.* The itemized bill for the services, which may be receipted or unpaid, must include all of the following information:

(1) The name and address of—

(i) The beneficiary;

(ii) The supplier or nonparticipating hospital that furnished the services; and

(iii) The physician who prescribed the services if they were furnished by a supplier other than the physician.

(2) The place where each service was furnished, e.g., home, office, independent laboratory, hospital.

(3) The date each service was furnished.

(4) A listing of the services in sufficient detail to permit determination of reasonable charges. (For example, a bill for ambulance service must specify the pick-up and delivery points.)

(5) The charges for each service.

(c) *Report of services furnished by a supplier.* For Medicare Part B services furnished by a supplier, the beneficiary claims may include the "Report of Services" portion of the appropriate claims form, completed by the supplier in accordance with HCFA instructions, in lieu of an itemized bill.

§ 424.36 Signature requirements.

(a) *General rule.* The beneficiary's own signature is required on the claim unless the beneficiary has died or the provisions of paragraph (b), (c), or (d) of this section apply.

(b) *Who may sign when the beneficiary is incapable.* If the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on his or her behalf by one of the following:

(1) The beneficiary's legal guardian.

(2) A relative or other person who receives social security or other governmental benefits on the beneficiary's behalf.

(3) A relative or other person who arranges for the beneficiary's treatment or exercises other responsibility for his or her affairs.

(4) A representative of an agency or institution that did not furnish the services for which payment is claimed

but furnished other care, services, or assistance to the beneficiary.

(5) A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished if the provider or nonparticipating hospital is unable to have the claim signed in accordance with paragraph (b) (1), (2), (3), or (4) of this section.

(c) *Who may sign if the beneficiary was not present for the service.* If a provider, nonparticipating hospital, or supplier files a claim for services that involved no personal contact between the provider, hospital, or supplier and the beneficiary (for example, a physician sent a blood sample to the provider for diagnostic tests), a representative of the provider, hospital, or supplier may sign the claim on the beneficiary's behalf.

(d) *Claims by entities that provide coverage complementary to Medicare.* A claim by an entity that provides coverage complementary to Medicare Part B may be signed by the entity on the beneficiary's behalf.

(e) *Acceptance of other signatures for good cause.* If good cause is shown, HCFA may honor a claim signed by a party other than those specified in paragraphs (a) through (c) of this section.

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.37 Evidence of authority to sign on behalf of the beneficiary.

(a) *Beneficiary incapable.* When a party specified in § 424.36(b) signs a claim or request for payment statement, he or she must also submit a brief statement that—

(1) Describes his or her relationship to the beneficiary; and

(2) Explains the circumstances that make it impractical for the beneficiary to sign the claim or statement.

(b) *Beneficiary not present for services.* When a representative of the provider, nonparticipating hospital, or supplier signs a claim or request for payment statement under § 424.36(c), he or she must explain why it was not possible to obtain the beneficiary's signature. (For example: "Patient not physically present for test.")

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.40 Request for payment effective for more than one claim.

(a) *Basic procedure.* A separate request for payment statement prescribed by HCFA and signed by the beneficiary (or by his or her representative) may be included in claims by reference, in the circumstances specified in paragraphs (b) through (d) of this section.

(b) *Claims filed by a provider or nonparticipating hospital.*—(1) *Inpatient services.* A signed request for payment statement, included in the first claim for Part A services furnished by a facility (a participating hospital or SNF, or a nonparticipating hospital that has elected to claim payment) during a beneficiary's period of confinement, may be effective for all claims for Part A services the facility furnishes that beneficiary during that confinement.

(2) *Home health services and outpatient physical therapy or speech pathology services.* A signed request for payment statement, included in the first claim for home health services or outpatient physical therapy or speech pathology services furnished by a provider under a plan of treatment, may be effective for all claims for home health services or outpatient physical therapy or speech pathology services furnished by the provider under that plan of treatment.

(c) *Signed statement in the provider record*—(1) *Services to inpatients.* A signed request for payment statement in the files of a participating hospital or SNF may be effective for all claims for services furnished to the beneficiary during a single inpatient stay in that facility—

(i) By the hospital or SNF;

(ii) By physicians, if their services are billed by the hospital or SNF in its name; or

(iii) By physicians who bill separately, if the services were furnished in the hospital or SNF.

(2) *Services to outpatients: Providers and renal dialysis facilities.* A signed request for payment statement retained in the provider's or facility's files may be effective indefinitely, for

all claims for services furnished to that beneficiary on an outpatient basis—

(i) By the provider or facility;

(ii) By physicians whose services are billed by the provider or facility in its name; or

(iii) By physicians who bill separately, if the services were furnished in the provider or facility.

(3) *Services to outpatients: Independent rural health clinics.* A signed request for payment statement retained in the clinic's files may be effective indefinitely for all claims for services furnished to that beneficiary by the clinic.

(d) *Signed statement in the supplier's record.* A signed request for payment statement retained in the supplier's file may be effective indefinitely subject to the following restrictions:

(1) This policy does not apply to unassigned claims for rental of durable medical equipment (DME).

(2) With respect to assigned claims for rental or purchase of DME, a new statement is required if another item of equipment is rented or purchased.

§ 424.44 Time limits for filing claims.

(a) *Basic limits.* Except as provided in paragraph (b) of this section, the claim must be mailed or delivered to the intermediary or carrier, as appropriate—

(1) On or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and

(2) On or before December 31 of the second following year for services that were furnished during the last 3 months of the calendar year.

(b) *Extension of filing time because of error or misrepresentation.* (1) The time for filing a claim will be extended if failure to meet the deadline in paragraph (a) of this section was caused by error or misrepresentation of an employee, intermediary, carrier, or agent of the Department that was performing Medicare functions and acting within the scope of its authority.

(2) The time will be extended through the last day of the 6th calendar month following the month in which the error or misrepresentation is corrected.

(c) *Extension of period ending on a nonworkday.* If the last day of the period allowed under paragraph (a) or (b) of this section falls on a Federal nonworkday (a Saturday, Sunday, legal holiday, or a day which by statute or Executive Order is declared to be a nonworkday for Federal employees), the time is extended to the next succeeding workday.

§ 424.45 What constitutes a claim for purposes of meeting the time limits.

A written statement of intent to claim Medicare benefits constitutes a claim if—

(a) The statement is filed with HCFA or any carrier or intermediary within the time limits specified in § 424.44;

(b) The statement indicates the intent to claim Medicare payment for specified services furnished to an identified beneficiary; and

(c) A claim that meets the requirements of § 424.32(a) is filed within 6 months after the month in which the intermediary or carrier, as appropriate, advises the claimant to file that claim.

Subpart D—To Whom Payment Is Ordinarily Made

§ 424.50 Scope.

(a) This subpart specifies to whom Medicare payment is ordinarily made for different kinds of services.

(b) Subpart E of this part sets forth provisions applicable in special situations.

(c) Subpart F of this part specifies the exceptional circumstances under which payment may be made to an assignee or reassignee.

§ 424.51 Payment to the provider.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare pays the provider for services furnished by a provider.

(b) *Exception.* Medicare pays the beneficiary for outpatient hospital services if the hospital has collected an amount in excess of the unmet deductible and coinsurance, as specified in § 489.30(b)(4) of this chapter.

§ 424.52 Payment to a nonparticipating hospital.

Medicare pays a nonparticipating hospital for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a U.S. hospital, if the hospital has in effect an election to claim payment in accordance with Subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a U.S. hospital, if the hospital meets the requirements of § 424.55 for payment as a supplier.

(c) Emergency or nonemergency inpatient services furnished by a foreign hospital if the hospital has in effect an election to claim payment in accordance with Subpart G of this part.

§ 424.53 Payment to the beneficiary.

Medicare pays the beneficiary for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a nonparticipating U.S. hospital that has not elected to claim payment in accordance with Subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a nonparticipating U.S. hospital, if the hospital does not receive assigned payment as a supplier under § 424.55.

(c) Emergency or nonemergency services furnished by a foreign hospital if the hospital does not have in effect an election to claim payment in accordance with Subpart H of this part.

(d) Physician and ambulance services furnished outside the United States.

(e) Services furnished by a supplier if the claim has not been assigned to the supplier.

§ 424.54 Payment to the beneficiary's legal guardian or representative payee.

Medicare may pay amounts due a beneficiary to the beneficiary's legal guardian or representative payee.

§ 424.55 Payment to the supplier

(a) Medicare pays the supplier for covered services if the beneficiary (or the person authorized to request payment on the beneficiary's behalf) assigns the claim to the supplier and the supplier accepts assignment.

(b) In accepting assignment, the supplier agrees to the following:

(1) To accept, as full charge for the service, the amount the carrier determines to be the reasonable charge.

(2) To limit charges to the beneficiary or any other source as follows:

(i) To collect nothing for those services for which Medicare pays 100 percent of the reasonable charge.

(ii) To collect only the amount of the unmet deductible, plus 20 percent of the difference between the reasonable charge and the unmet deductible for those services for which Medicare pays 80 percent of that difference.

(3) Not to charge the beneficiary when Medicare paid for services determined to be "not reasonable or necessary" if—

(i) The beneficiary was without fault in the overpayment; and

(ii) The determination that the payment was incorrect was made by the carrier after the third year following the year in which the carrier sent notice to the beneficiary that it approved the payment.

§ 424.56 Payment to a beneficiary and to a supplier.

(a) *Conditions for split payment.* If the beneficiary assigns the claim after paying part of the bill, payment may be made partly to the beneficiary and partly to the supplier.

(b) *Payment to the supplier.* Payment to the supplier who submits the assigned claim is for whichever of the following amounts is less:

(1) The reasonable charge minus the amount the beneficiary had already paid to the supplier; or

(2) The full Part B benefit due for the services furnished.

(c) *Payment to the beneficiary.* Any part of the Part B benefit which, on the basis of paragraph (b) of this section, is not payable to the supplier, is paid to the beneficiary.

(d) *Examples.*

Example 1. An assigned bill of $300 on which partial payment of $100 has been made is submitted to the carrier. The carrier determines that $300 is the reasonable charge for the service furnished. Total payment due is 80 percent of $300 or $240. Of this amount, $200 (the difference between the $100 partial payment and the $300 reasonable charge) is paid to the supplier. The remaining $40 is paid to the beneficiary.

Example 2. An assigned bill of $325 on which partial payment of $275 has been made is submitted to the carrier. The carrier determines that $275 is the reasonable charge for the services. Total payment due is 80 percent of $275 or $220. The $220 is paid to the beneficiary, since any payment to the supplier, when added to the $275 partial payment would exceed the reasonable charge for the services furnished.

[53 FR 6641, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart E—To Whom Payment is Made in Special Situations

§ 424.60 Scope.

(a) This subpart sets forth provisions applicable to payment after the beneficiary's death and payment to entities that provide coverage complementary to Medicare Part B.

(b) The provisions applicable to payment for services excluded as custodial care or services not reasonable and necessary are set forth in §§ 405.332 through 405.336 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.62 Payment after beneficiary's death: Bill has been paid.

(a) *Scope.* This section specifies the persons whom Medicare pays, and the conditions for payments, when the beneficiary has died and the bill has been paid.

(b) *Situation.* (1) The beneficiary has received covered services for which he could receive direct payment under § 424.53.

(2) The beneficiary died without receiving Medicare payment.

(3) The bill has been paid.

(c) *Persons whom Medicare pays.* In the situation described in paragraph (b) of this section, Medicare pays the following persons in the specified circumstances:

(1) The person or persons who, without a legal obligation to do so, paid for the services with their own funds, before or after the beneficiary's death.

(2) The legal representative of the beneficiary's estate if the services were paid for by the beneficiary before he or she died, or with funds from the estate.

(3) If the deceased beneficiary or his or her estate paid for the services and no legal representative of the estate has been appointed, the survivors, in the following order of priority:

(i) The person found by SSA to be the surviving spouse, if he or she was either living in the same household with the deceased at the time of death, or was, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(ii) The child or children, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(iii) The parent or parents, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent);

(iv) The person found by SSA to be the surviving spouse who was not living in the same household with the deceased at the time of death and was not, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(v) The child or children who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(vi) The parent or parents who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent).

(4) If none of the listed relatives survive, no payment is made.

(5) If the services were paid for by a person other than the deceased beneficiary, and that person died before payment was completed, Medicare does not pay that person's estate. Medicare pays a surviving relative of the deceased beneficiary in accordance with the priorities in paragraph (c)(3) of this section. If none of those relatives survive, Medicare pays the legal representative of the deceased beneficiary's estate. If there is no legal representative of the estate, no payment is made.

(d) *Amount of payment.* The amount of payment is the amount due, including unnegotiated checks issued for the purpose of making direct payment to the beneficiary.

(e) *Conditions for payment.* For payment to be made under this section—

(1) The person who claims payment must meet the following requirements:

(i) Submit a claim on a HCFA-prescribed form and an itemized bill in accordance with the requirements of this subpart. (See paragraph (g) of this section for an exception.)

(ii) Provide evidence that the services were furnished if the intermediary or carrier requests it.

(iii) Provide evidence of payment of the bill and of the identity of the person who paid it.

(2) If a person claims payment as the legal representative of the deceased beneficiary's estate, he or she must also submit a copy of the papers showing appointment as legal representative.

(3) If a person claims payment as a survivor of the beneficiary, he or she must also submit evidence, if the intermediary or carrier requests it, that he or she is highest on the priority list of paragraph (c)(3) of this section.

(f) *Evidence of payment.* Evidence of payment may be—

(1) A receipted bill, or a properly completed "Report of Services" section of a claim form, showing who paid the bill;

(2) A cancelled check;

(3) A written statement from the provider or supplier or an authorized staff member; or

(4) Other probative evidence.

(g) *Exception: Claim submitted before beneficiary died.* If a claim and itemized bill has been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form and itemized bill is not required; any written request by the person seeking payment is sufficient.

§ 424.64 Payment after beneficiary's death: Bill has not been paid.

(a) *Scope.* This section specifies whom Medicare pays, and the conditions for payment when the beneficiary has died and the bill has not been paid.

(b) *Situation.* (1) The beneficiary has received covered Part B services furnished by a physician or other supplier.

(2) The beneficiary died without making an assignment to the physician or other supplier or receiving Medicare payment.

(3) The bill has not been paid.

(c) *To whom payment is made.* In the situation described in paragraph (b) of this section, Medicare pays as follows:

(1) *Payment to the supplier.* Medicare pays the physician or other supplier if he or she—

(i) Files a claim on a HCFA-prescribed form in accordance with the applicable requirements of this subpart;

(ii) Upon request from the carrier, provides evidence that the services for which it claims payment were, in fact, furnished; and

(iii) Agrees in writing to accept the reasonable charge as the full charge for the services.

(2) *Payment to a person who assumes legal obligation to pay for the services.* If the physician or other supplier does not agree to accept the reasonable charge as full charge for the service, Medicare pays any person who submits to the carrier all of the following:

(i) A statement indicating that he or she has assumed legal obligation to pay for the services.

(ii) A claim on a HCFA-prescribed form in accordance with the requirements of this subpart. (If a claim had been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form is not required; a written request by the person seeking payment meets the requirement for a claim.)

(iii) An itemized bill that identifies the claimant as the person to whom the physician or other supplier holds responsible for payment. (If such an itemized bill had been submitted by or on behalf of the beneficiary before he or she died, submission of another itemized bill is not required.)

(iv) If the intermediary or carrier requests it, evidence that the services were actually furnished.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.66 Payment to entities that provide coverage complementary to Medicare Part B.

(a) *Conditions for payment.* Medicare may pay an entity for Part B services furnished by a physician or other supplier if the entity meets all of the following requirements:

(1) Provides coverage of the service under a complementary health benefit plan (this is, the coverage that the plan provides is complementary to Medicare benefits and covers only the amount by which the Part B payment falls short of the approved charge for the service under the plan).

(2) Has paid the person who provided the service an amount (including the amount payable under the Medicare program) that the person accepts as full payment.

(3) Has the written authorization of the beneficiary (or of a person authorized to sign claims on his behalf under § 405.1679) to receive the Part B payment for the services for which the entity pays.

(4) Relieves the beneficiary of liability for payment for the service and will not seek any reimbursement from the beneficiary, his or her survivors or estate.

(5) Submits any information HCFA or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program.

(6) Identifies and excludes from its requests for payment all services for which Medicare is the secondary payer.

(b) *Services paid by the entity.* An entity is not required to pay and claim reimbursement for all Part B services furnished to members of its plans. However, if it does not pay and claim reimbursement for all those services, it must establish in advance precise criteria for identifying the services for which it will pay and claim reimbursement.

[53 FR 28388, July 28, 1988]

Subpart F—Limitations on Assignment and Reassignment of Claims

§ 424.70 Basis and scope.

(a) *Statutory basis.* This subpart implements sections 1815(c) and 1842(b)(6) of the Act, which establish limitations on who may receive payments due a provider or supplier of services or a beneficiary.

(b) *Scope.* This subpart—

(1) Prohibits the assignment, reassignment, or other transfer of the right to Medicare payments except under specified conditions;

(2) Sets forth the sanctions that HCFA may impose on a provider or supplier that violates this prohibition, or on a supplier that violates the conditions to which it agreed in accepting assignment from the individual; and

(3) Specifies the conditions for payment under court-ordered assignments or reassignments.

§ 424.71 Definitions.

As used in this subpart, unless the context indicates otherwise—

"Court of competent jurisdiction" means a court that has jurisdiction over the subject matter and the parties before it.

"Facility" means a hospital or other institution that furnishes health care services to inpatients.

"Health care delivery system" or *"system"* means a public or private organization for delivering health services. The term includes, but is not limited to, clinics and health care prepayment plans.

"Power of attorney" means any written documents by which a principal authorizes an agent to—

(1) Receive, in the agent's name, any payments due the principal;

(2) Negotiate checks payable to the principal; or

(3) Receive, in any other manner, direct payment of amounts due the principal.

§ 424.73 Prohibition of assignment of claims by providers.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a provider to any other person under assignment, or power of attorney, or any other direct payment arrangement.

(b) *Exceptions to the prohibition*—(1) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by the provider.

(2) *Payment under assignment established by court order.* Medicare may pay under an assignment established by, or in accordance with, the order of a court of competent jurisdiction if the assignment meets the conditions set forth in § 424.90.

(3) *Payment to an agent.* Medicare may pay an agent who furnishes billing and collection services to the provider if the following conditions are met:

(i) The agent receives the payment under an agency agreement with the provider;

(ii) The agent's compensation is not related in any way to the dollar amounts billed or collected;

(iii) The agent's compensation is not dependent upon the actual collection of payment;

(iv) The agent acts under payment disposition instructions that the provider may modify or revoke at any time; and

(v) The agent, in receiving the payment, acts only on behalf of the provider.

Payment to an agent will always be made in the name of the provider.

§ 424.74 Termination of provider agreement.

HCFA may terminate a provider agreement, in accordance with § 489.53(a)(1) of this chapter, if the provider—

(a) Executes or continues a power of attorney, or enters into or continues any other arrangement, that authorizes or permits payment contrary to the provisions of this subpart; or

(b) Fails to furnish, upon request by HCFA or the intermediary, evidence necessary to establish compliance with the requirements of this subpart.

§ 424.80 Prohibition of reassignment of claims by suppliers.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a supplier under an assignment to any other person under reassignment, power of attorney, or any other direct arrangement.

(b) *Exceptions to the basic rule*—(1) *Payment to employer.* Medicare may pay the supplier's employer if the supplier is required, as a condition of employment, to turn over to the employer the fees for his or her services.

(2) *Payment to a facility.* Medicare may pay the facility in which the services were furnished if there is a contractual arrangement between the facility and the supplier under which the facility bills for the supplier's services.

(3) *Payment to health care delivery system.* Medicare may pay a health care delivery system if there is a contractual arrangement between the system and the supplier under which the system bills for the supplier's services.

(4) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under a reassignment by the supplier.

(5) *Payment under a reassignment established by court order.* Medicare may pay under a reassignment established by, or in accordance with, the order of a court competent jurisdiction, if the reassignment meets the conditions set forth in § 424.90.

(6) *Payment to an agent.* Medicare may pay an agent who furnishes billing and collection services to the supplier, or to the employer, facility, or system specified in paragraphs (b) (1), (2) and (3) of this section, if the conditions of § 411.73(b)(3) for payment to a provider's agent are met by the agent

of the supplier or of the employer, facility, or system. Payment to an agent will always be made in the name of the supplier or the employer, facility, or system.

(c) ***Rules applicable to an employer, facility, or system.*** An employer, facility, or system that may receive payment under paragraph (b)(1), (b)(2), or (b)(3) of this section will itself be considered the supplier of those services for purposes of the rules of Subparts C, D, and E of this part.

§ 424.82 Revocation of right to receive assigned benefits.

(a) *Scope.* This section sets forth the conditions and procedures for revocation of the right of a supplier or other party to receive Medicare payments.

(b) *Definition.* As used in this section, *"other party"* means an employer, facility, or health care delivery system to which Medicare may make payment under § 424.80(b) (1), (2), or (3).

(c) *Basis for revocation.* HCFA may revoke the right of a supplier or other party to receive Medicare payments if the supplier or other party, after warning by HCFA or the carrier—

(1) Violates the terms of assignment in § 424.55(b).

(2) Continues collection efforts or fails to refund moneys incorrectly collected, in violation of the terms of assignment in § 424.55(b).

(3) Executes or continues in effect a reassignment or power of attorney or any other arrangement that seeks to obtain payment contrary to the provisions of § 424.80; or

(4) Fails to furnish evidence necessary to establish its compliance with the requirements of § 424.80.

(d) *Proposed revocation: Notice and opportunity for review.* If HCFA proposes to revoke the right to payment in accordance with paragraph (c) of this section, it will send the supplier or other party a written notice that—

(1) States the reasons for the proposed revocation; and

(2) Provides an opportunity for the supplier or other party to submit written argument and evidence against the proposed revocation. HCFA usually allows 15 days from the date on the notice, but.may extend or reduce the time as circumstances require.

(e) *Actual revocation: Timing, notice, and opportunity for hearing*—(1) *Timing.* HCFA determines whether to revoke after considering any written argument or evidence submitted by the supplier or other party or, if none is submitted, at the expiration of the period specified in the notice of proposed revocation.

(2) *Notice and opportunity for hearing.* The notice of revocation specifies—

(i) The reasons for the revocation;

(ii) That the revocation is effective as of the date on the notice;

(iii) That the supplier or other party may, within 60 days from the date on the notice (or a longer period if the notice so specifies), request an administrative hearing and may be represented by counsel or other qualified representative.

(iv) That the carrier will withhold payment on any claims submitted by the supplier or other party until the period for requesting a hearing expires or, if a hearing is requested, until the hearing officer issues a decision;

(v) That if the hearing decision reverses the revocation, the carrier will pay the supplier's or other party's claims; and

(vi) That if a hearing is not requested or the hearing decision upholds the revocation, payment will be made to the beneficiary or to another person or agency authorized to receive payment on his or her behalf.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.83 Hearings on revocation of right to receive assigned benefits.

If the supplier or other party requests a hearing under § 424.82(e)(2)—

(a) The hearing is conducted—

(1) By a HCFA hearing official who was not involved in the decision to revoke; and

(2) In accordance with the procedures set forth in §§ 405.824 through 405.833 (but excepting § 405.832(d)) and 405.860 through 405.872 of this chapter. In applying those procedures, "HCFA" is substituted for "carrier";

and "hearing official", for "hearing officer".

(b) As soon as practicable after the close of the hearing, the official who conducted it issues a hearing decision that—

(1) Is based on all the evidence presented at the hearing and included in the hearing record; and

(2) Contains findings of fact and a statement of reasons.

§ 424.84 Final determination on revocation of right to receive assigned benefits.

(a) *Basis of final determination.*—(1) *Final determination without a hearing.* If the supplier or other party does not request a hearing, HCFA's revocation determination becomes final at the end of the period specified in the notice of revocation.

(2) *Final determination following a hearing.* If there is a hearing, the hearing decision constitutes HCFA's final determination.

(b) *Notice of final determination.* HCFA sends the supplier or other party a written notice of the final determination and, if there was a hearing, includes a copy of the hearing decision.

(c) *Application of the final determination*—(1) A final determination not to revoke is the final administrative decision by HCFA on the matter.

(2) A final determination to revoke remains in effect until HCFA finds that the reason for the revocation has been removed and that there is reasonable assurance that it will not recur.

(d) *Effect of revocation when supplier or other party has a financial interest in another entity.* Revocation of the party's right to accept assignment also applies to any corporation, partnership, or other entity in which the party, directly or indirectly, has or acquires all or all but a nominal part of the financial interest.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.86 Prohibition of assignment of claims by beneficiaries.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a beneficiary under § 424.53 to any other person under assignment, power of attorney, or any other direct payment arrangement.

(b) *Exceptions.*—(1) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by a beneficiary (or by the beneficiary's legal guardian or representative payee).

(2) *Payment under an assignment established by court order.* Medicare may pay under an assignment established by, or in accordance with, a court order if the assignment meets the conditions set forth in § 424.90.

§ 424.90 Court ordered assignments: Conditions and limitations.

(a) *Conditions for acceptance.* An assignment or reassignment established by or in accordance with a court order is effective for Medicare payments only if—

(1) Someone files a certified copy of the court order and of the executed assignment or reassignment (if it was necessary to execute one) with the intermediary or carrier responsible for processing the claim; and

(2) The assignment or reassignment—

(i) Applies to all Medicare benefits payable to a particular person or entity during a specified or indefinite time period; or

(ii) Specifies a particular amount of money, payable to a particular person or entity by a particular intermediary or carrier.

(b) *Retention of authority to reduce interim payments to providers.* A court-ordered assignment does not preclude the intermediary or carrier from reducing interim payments, as set forth in § 413.64(i) of this chapter, if the provider or assignee is in imminent danger of insolvency or bankruptcy.

(c) *Liability of the parties.* The party that receives payments under a court-ordered assignment or reassignment that meets the conditions of paragraph (a) of this section and the party that would have received payment if the court order had not been issued are jointly and severally responsible for any Medicare overpayment to the former.

Subpart G—Special Conditions: Emergency Services Furnished by a Nonparticipating Hospital

§ 424.100 Scope.

This subpart sets forth procedures and criteria that are followed in determining whether Medicare will pay for emergency services furnished by a hospital that is located in the United States and does not have in effect a provider agreement, that is, an agreement to participate in Medicare.

§ 424.101 Definitions.

As used in this subpart, unless the context indicates otherwise—

"Emergency services" means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

"Hospital" means a facility that—

(1) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled;

(2) Is not primarily engaged in providing skilled nursing care and related services for patients who require medical or nursing care, as described in section 1861(j)(1)(A) of the Act;

(3) Provides 24-hour nursing service in accordance with section 1861(e)(5) of the Act; and

(4) Is licensed, or is approved as meeting the standards for licensing, by the State or local licensing agency.

"Reasonable charges" means customary charges insofar as they are reasonable.

§ 424.102 Situations that do not constitute an emergency.

Without additional evidence of a threat to life or health, the following situations do not in themselves indicate a need for emergency services:

(a) Lack of care at home.

(b) Lack of transportation to a participating hospital.

(c) Death of the patient in the hospital.

§ 424.103 Conditions for payment for emergency services.

Medicare pays for emergency services furnished to a beneficiary by a nonparticipating hospital or under arrangements made by such a hospital if the conditions of this section are met.

(a) *General requirements.* (1) The services are of the type that Medicare would pay for if they were furnished by a participating hospital.

(2) The hospital has in effect an election to claim payment for all emergency services furnished in a calendar year in accordance with § 424.104.

(3) The need for emergency services arose while the beneficiary was not an inpatient in a hospital.

(4) In the case of inpatient hospital services, the services are furnished during a period in which the beneficiary could not be safely discharged or transferred to a participating hospital or other institution.

(5) The determination that the hospital was the most accessible hospital available and equipped to furnish the services is made in accordance with § 424.106.

(b) *Medical information requirements.* A physician (or, if appropriate, the hospital) submits medical information that—

(1) Describes the nature of the emergency and specifies why it required that the beneficiary be treated in the most accessible hospital;

(2) Establishes that all the conditions in paragraph (a) of this section are met; and

(3) Indicates when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.104 Election to claim payment for emergency services furnished during a calendar year.

(a) *Terms of the election.* The hospital agrees to the following:

(1) To comply with the provisions of Subpart C of Part 489 of this chapter relating to charges for items and services the hospital may make to the beneficiary, or any other person on his or her behalf.

(2) To comply with the provisions of Subpart D of Part 489 of this chapter relating to proper disposition of monies incorrectly collected from, or on behalf of a beneficiary.

(3) To request payment under the Medicare program based on amounts specified in § 413.74 of this chapter.

(b) *Filing of election statement.* An election statement must be filed on a form designated by HCFA, signed by an authorized official of the hospital, and either received by HCFA, or postmarked, before the close of the calendar year of election.

(c) *Acceptance and effective date of election.* If HCFA accepts the election statement, the election is effective as of the earliest day of the calendar year of election from which HCFA determines the hospital has been in continuous compliance with the requirements of section 1814(d) of the Act.

(d) *Appeal by hospital.* Any hospital dissatisfied with a determination that it does not qualify to claim reimbursement shall be entitled to appeal the determination as provided in Part 498 of this chapter.

(e) *Conditions for reinstatement after notice of failure to continue to qualify.* If HCFA has notified a hospital that it no longer qualifies to receive reimbursement for a calendar year, HCFA will not accept another election statement from that hospital until HCFA finds that—

(1) The reason for its failure to qualify has been removed; and

(2) There is reasonable assurance that it will not recur.

§ 424.106 Criteria for determining whether the hospital was the most accessible.

(a) *Basic requirement.* (1) The hospital must be the most accessible one available and equipped to furnish the services.

(2) HCFA determines accessibility based on the factors specified in paragraphs (b) and (c) of this section and the conditions set forth in paragraph (d) of this section.

(b) *Factors that are considered.* HCFA considers the following factors in determining whether a nonparticipating hospital in a rural area meets the accessibility requirements:

(1) The relative distances of participating and nonparticipating hospitals in the area.

(2) The transportation facilities available to these hospitals.

(3) The quality of the roads to each hospital.

(4) The availability of beds at each hospital.

(5) Any other factors that bear on whether or not the services could be provided sooner in the nonparticipating hospitals than in a participating hospital in the general area.

In urban and suburban areas where both participating and nonparticipating hospitals are similarly available, HCFA presumes that the services could have been provided in a participating hospital unless clear and convincing evidence shows that there was a medical or practical need to use the nonparticipating hospital.

(c) *Factors that are not considered.* HCFA gives no consideration to the following factors in determining whether the nonparticipating hospital was the most accessible hospital:

(1) The personal preference of the beneficiary, the physician, or members of the family.

(2) The fact that the attending physician did not have staff privileges in a participating hospital which was available and the most accessible to the beneficiary.

(3) The location of previous medical records.

(d) *Conditions under which the accessibility requirement is met.* If a beneficiary must be taken to a hospital immediately for required diagnosis and treatment, the nonparticipating hospital meets the accessibility requirement if—

(1) It was the nearest hospital to the point where the emergency occurred, it was medically equipped to handle the type of emergency, and it was the most accessible, on the basis of the factors specified in paragraph (b) of this section; or

(2) There was a closer participating hospital equipped to handle the emergency, but the participating hospital did not have a bed available or would not accept the individual.

§ 424.108 Payment to a hospital.

(a) *Conditions for payment.* Medicare pays the hospital for emergency services if the hospital—

(1) Has in effect a statement of election to claim payment for all covered emergency services furnished during a calendar year, in accordance with § 424.104;

(2) Claims payment in accordance with § 424.32; and

(3) Submits evidence requested by HCFA to establish that the services meet the requirements of this subpart.

(b) *Subsequent claims.* If the hospital files subsequent claims because the initial claim did not include all the services furnished, those claims must include physicians' statements that—

(1) Contain sufficient information to clearly establish that, when the additional services were furnished, the emergency still existed; and

(2) Indicate when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.109 Payment to the beneficiary.

Medicare pays the beneficiary for emergency services if the following conditions are met:

(a) The hospital does not have in effect an election to claim payment.

(b) The beneficiary, or someone on his or her behalf, submits—

(1) A claim that meets the requirements of § 424.32;

(2) An itemized hospital bill; and

(3) Evidence requested by HCFA to establish that the services meet the requirements of this subpart.

Subpart H—Special Conditions: Services Furnished in a Foreign Country

§ 424.120 Scope.

This subpart sets forth the conditions for payment for services furnished in a foreign country.

§ 424.121 Scope of payments.

Subject to the conditions set forth in this subpart—

(a) Medicare Part A pays, in the amounts specified in § 413.74 of this chapter, for emergency and nonemergency inpatient hospital services furnished by a foreign hospital.

(b) Medicare Part B pays for certain physicians' services and ambulance services furnished in connection with covered inpatient care in a foreign hospital, as specified in § 424.124.

(c) All other services furnished outside the United States are excluded from Medicare coverage, as specified in § 405.313 of this chapter.

§ 424.122 Conditions for payment for emergency inpatient hospital services.

Medicare Part A pays for emergency inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) At the time of the emergency that required the inpatient hospital services, the beneficiary was—

(1) In the United States; or

(2) In Canada traveling between Alaska and another State without unreasonable delay and by the most direct route.

(b) The foreign hospital was closer to, or more accessible from, the site of the emergency than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The conditions for payment for emergency services set forth in § 424.103 are met.

(d) The hospital is a hospital as defined in § 424.101, and is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located.

(e) The determination of whether the hospital was more accessible is made in accordance with § 424.106.

§ 424.123 Conditions for payment for nonemergency inpatient services furnished by a hospital closer to the individual's residence.

Medicare Part A pays for inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) The beneficiary is a resident of the United States.

(b) The foreign hospital is closer or more accessible to the beneficiary's residence than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The foreign hospital is—

(1) A hospital as defined in § 424.101 and, it is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located; and

(2) Accredited by the Joint Commission on Accreditation of Hospitals (JCAH) or accredited or approved by a program of the country where it is located under standards that HCFA finds to be essentially equivalent to those of the JCAH.

(d) The services are covered services that Medicare would pay for if they were furnished by a participating hospital.

§ 424.124 Conditions for payment for physician services and ambulance services.

(a) *Basic rules.* Medicare Part B pays for physician and ambulance services if—

(1) They are furnished—

(i) To an individual who is entitled to Part B benefits; and

(ii) In connection with covered inpatient hospital services; and

(2) They meet the conditions set forth in paragraphs (b) and (c) of this section.

(b) *Physician services.* (1) The physician services are services covered under Medicare Part B and are furnished—

(i) In the hospital, during a period of covered inpatient services; or

(ii) Outside the hospital, on the day of admission and for the same condition that required inpatient admission; and

(2) The physician is legally authorized to practice in the country where he or she furnishes the services.

(c) *Ambulance services.* The ambulance services are—

(1) Necessary because the use of other means of transportation is contraindicated by the beneficiary's condition; and

(2) Furnished by an ambulance that meets the definition in § 410.140 of this chapter.

[53 FR 6646, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.126 Payment to the hospital.

(a) *Conditions for payment.* Medicare pays the hospital if it—

(1) Has in effect an election that—

(i) Meets the requirements set forth in § 424.104; and

(ii) Reflects the hospital's intent to claim for all covered services furnished during a calendar year.

(2) Claims payment in accordance with §§ 424.32 and 413.74 of this chapter, and

(3) Submits evidence requested by HCFA to establish that the services meet the requirements of this subpart.

(b) *Amount of payment.* Payment is made (in accordance with § 413.74 of this chapter) on the basis of 100 percent of the hospital's customary charges, subject to the applicable deductible and coinsurance provisions set forth elsewhere in this chapter.

§ 424.127 Payment to the beneficiary.

(a) *Conditions for payment of inpatient hospital services.* Medicare pays the beneficiary if—

(1) The hospital does not have in effect an election to claim payment; and

(2) The beneficiary, or someone on his or her behalf, submits—

(i) A claim in accordance with § 424.32;

(ii) An itemized hospital bill; and

(iii) Evidence requested by HCFA to establish that the services meet the requirements of this subpart.

(b) *Amount payable for inpatient hospital services.* The amount payable to the beneficiary is determined in accordance with § 424.109(b).

(c) *Conditions for payment for Part B services.* Medicare pays the beneficiary for physicians' services and ambulance services as specified in § 424.121, if an itemized bill for the services is submitted by the beneficiary or someone on his or her behalf and the conditions of § 424.126(a) (2) and (3) are met.

(d) The amount payable to the beneficiary is determined in accordance with § 410.152 of this chapter.

Subparts I–L [Reserved]

Subpart M—Replacement and Reclamation of Medicare Payments

§ 424.350 Replacement of U.S. government checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

(a) *Responsibility.* The Treasury Department is responsible for the investigation and settlement of claims in connection with Treasury checks issued on behalf of HCFA.

(b) *Action by HCFA.* HCFA forwards reports of lost, stolen, defaced, mutilated, destroyed, or forged Treasury checks to the Treasury Department disbursing center responsible for issuance of the checks.

(c) *Action by the Treasury Department.* The Treasury Department will replace and begin reclamation of Treasury checks in accordance with Treasury Department regulations (31 CFR Parts 235, 240 and 245).

§ 424.352 Replacement of intermediary and carrier checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

(a) *HCFA's responsibility.* HCFA is responsible for coordinating the investigation and settlement of claims in connection with intermediary and carrier checks, including the determination that a check endorsement has been forged.

(b) *Action by HCFA.* HCFA—

(1) Analyzes each check suspected of having a forged endorsement to determine the authenticity of the endorsement;

(2) Grants an independent administrative review, upon request, to any payee dissatisfied with its determination; and

(3) Forwards reports concerning lost, stolen, defaced, mutilated, destroyed, or forged checks to the issuing office of the appropriate intermediary or carrier.

(c) *Action by carrier or intermediary: Outstanding check that is lost, stolen, defaced, mutilated, or destroyed.* (1) If the check has been lost or stolen and has not been paid, the carrier or intermediary must stop payment on the check and issue another check.

(2) If the check has been defaced, mutilated, or destroyed, the carrier or intermediary must recover any available remains of the check and issue a substitute check.

(d) *Action by carrier or intermediary: Forged endorsement.* The carrier or intermediary must make settlement in favor of the payee before recovering the amount of the check if—

(1) The facts show that the check was paid on a forged endorsement and the payee did not participate, directly or indirectly, in the proceeds of that payment: and

(2) The payee, or the payee's authorized representative, after examining the check or a copy of it, states in writing that to the best of his or her knowledge or belief the endorsement is not the payee's.

[53 FR 6647, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.354 Reclamation proceedings: Checks issued by carriers or intermediaries.

Checks issued by carriers and intermediaries are drawn on commercial banks and are not subject to the Federal laws and Treasury Department regulations that govern Treasury checks. Accordingly, when HCFA determines that a check has been paid on a forged endorsement, the carrier or intermediary must take appropriate action to recover the amount of the check, in accordance with applicable State law.

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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42 CFR CHAPTER IV (PARTS 400–429)

HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

	42 CFR
American Hospital Association	
Available from: Health Care Financing Administration, Office of Management and Budget, Division of Communication Services, Printing and Publishing Branch, Gwynn Oak Bldg., Baltimore, MD 21235	
Chart of Accounts for Hospitals (1973 Ed.)	405.415(b)(7)(i)
American Lung Association	
(Formerly National Tuberculosis Association) 1740 Broadway, New York, NY 10019	
Diagnostic Standards and Classification of Tuberculosis (1974 Ed.)	405.1039(b)(2)
American National Standards Institute	
Available from Engineering Societies' Library, 345 E. 47th St., New York, NY 10017	
ANSI A117.1–1971 Specifications for Making Buildings and Facilities Accessible to and Usable by Physically Handicapped People.	405.1134(c)
American Psychiatric Association	
1700 18th St. NW., Washington, DC 20009	
Diagnostic and Statistical Manual of Mental Disorders, 1980 (3rd Ed.)	405.243(b); 405.1037(a)(12)
Association for the Advancement of Medical Instrumentation	
901 North Fort Myers Drive, Suite 602, Arlington, VA 22209–1699	
Recommended Practice for Reuse of Hemodialyzers	405.2150
National Academy of Sciences	
Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418	
Recommended Dietary Allowances Current Edition, 1980 (9th Ed.)	405.1025(c)(2)
National Fire Protection Association	
Batterymarch Park, Quincy, MA 02269	
NFPA Standard No. 101, Life Safety Code 1985	405.1022(b); 405.1134(a)

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National Oceanic and Atmospheric Administration	15, IX; 50, II, III, IV, VI
National Park Service	36, I
National Railroad Adjustment Board	29, III
National Railroad Passenger Corporation (AMTRAK)	49, VII
National Science Foundation	45, VI; 48,25
National Security Council	32, XXI
National Security Council and Office of Science and Technology Policy	47, II
National Telecommunications and Information Administration	15, XXIII
National Transportation Safety Board	49, VIII
Navajo and Hopi Indian Relocation Commission	25, IV
Navy Department	32, VI; 48, 52
Neighborhood Reinvestment Corporation	24, XXV
Nuclear Regulatory Commission	10, I
Occupational Safety and Health Administration	29, XVII
Occupational Safety and Health Review Commission	29, XX
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Offices of Independent Counsel, Department of Justice	28, VI
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Peace Corps	22, III
Pennsylvania Avenue Development Corporation	36, IX
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Personnel Management, Office of	5, I; 45, VIII; 48, 17
Federal Employees Health Benefits Acquisition Regulation	48, 16
Postal Rate Commission	39, III
Postal Service, United States	39, I
Postsecondary Education, Office of	34, VI
President's Commission on White House Fellowships	1, IV
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Prisons, Bureau of	28, V
Productivity, Technology and Innovation, Assistant Secretary (Commerce)	37, IV
Property Management Regulations System, Federal	41, Subtitle C
Public Contracts, Department of Labor	41, 50
Public Health Service	42, I
Railroad Retirement Board	20, II
Reclamation Bureau	43, I
Refugee Resettlement, Office of	45, IV
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Saint Lawrence Seaway Development Corporation	33, IV
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Science and Technology Policy, Office of, and National Security Council	47, II
Secret Service	31, IV
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Social Security Administration	20, III; 45, IV
Soil Conservation Service	7, VI
Solar Energy and Energy Conservation Bank, Department of Housing and Urban Development	24, XI
Soldiers' and Airmen's Home, United States	5, XI

Agency	CFR Title, Subtitle or Chapter
Special Education and Rehabilitative Services, Office of	**34, III**
State Department	**22, I**
Federal Acquisition Regulation	**48, 6**
Surface Mining and Reclamation Appeals, Board of	**30,III**
Susquehanna River Basin Commission	**18, VIII**
Tennessee Valley Authority	**18, XIII**
Trade Representative, United States, Office of	**15, XX**
Transportation, Department of	**44, IV**
Coast Guard	**33, I; 46, I, III; 49, IV**
Commercial Space Transportation, Office of	**14, III**
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Federal Aviation Administration	**14, I**
Federal Highway Administration	**23, I, II; 49, III**
Federal Railroad Administration	**49, II**
Maritime Administration	**46, II**
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Urban Mass Transportation Administration	**49, VI**
Transportation, Office of, Department of Agriculture	**7, XXXIII**
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Treasury Department	**17, IV**
Alcohol, Tobacco and Firearms, Bureau of	**27, I**
Comptroller of the Currency	**12, I**
Customs Service, United States	**19, I**
Engraving and Printing, Bureau of	**31, VI**
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Federal Law Enforcement Training Center	**31, VII**
Fiscal Service	**31, II**
Foreign Assets Control, Office of	**31, V**
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United States Information Agency	**22, V; 48, 19**
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United States Postal Service	**39, I**
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United States Trade Representative, Office of	**15, XX**
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Vocational and Adult Education, Office of	**34, IV**
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World Agriculture Outlook Board	**7, XXXVIII**

Redesignation Table I

At 42 FR 52826, September 30, 1977, regulations formerly appearing in Title 42 as Part 101 were redesignated and transferred into Parts 460 through 480 of this title.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

New section	Old section	New section	Old section
460.1	101.1	460.38	101.38
460.2	101.2	460.39	101.39
460.2a	101.2a	460.40	101.40
460.3	101.3	460.41	101.41
460.4	101.4	460.42	101.42
460.5	101.5	460.43	101.43
460.6	101.6	460.44	101.44
460.7	101.7	460.45	101.45
460.8	101.8	460.46	101.46
460.9	101.9	460.47	101.47
460.10	101.10	460.48	101.48
460.11	101.11	460.49	101.49
460.12	101.12	460.50	101.50
460.13	101.13	460.51	101.51
460.14	101.14	460.52	101.52
460.15	101.15	460.53	101.53
460.16	101.16	460.54	101.54
460.17	101.17	460.55	101.55
460.18	101.18	460.56	101.56
460.19	101.19	461.1	101.101
460.20	101.20	461.2	101.102
460.21	101.21	461.3	101.103
460.22	101.22	461.4	101.104
460.23	101.23	461.5	101.105
460.24	101.24	461.6	101.106
460.25	101.25	461.7	101.107
460.26	101.26	473.1	101.1401
460.27	101.27	473.2	101.1402
460.28	101.28	473.3	101.1403
460.29	101.29	473.4	101.1404
460.30	101.30	473.5	101.1405
460.31	101.31	473.6	101.1406
460.32	101.32	480.1	101.2101
460.33	101.33	480.2	101.2102
460.34	101.34	480.3	101.2103
460.35	101.35	480.4	101.2104
460.36	101.36	480.5	101.2105
460.37	101.37	480.6	101.2106

Redesignation Table II

At 42 FR 52827, September 30, 1977, regulations formerly appearing in Title 45 as Parts 246, 248, 249, 250, 251 and 252 were redesignated and transferred into Title 42 as Parts 446, 448, 449, 450, 451 and 452, respectively.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

New section (Title 42)	Old section (Title 45)
446.10	246.10
446.160	246.160
448.1	248.1
448.2	248.2
448.3	248.3
448.4	248.4
448.10	248.10
448.11	248.11
448.21	248.21
448.30	248.30
448.40	248.40
448.50	248.50
448.60	248.60
448.70	248.70
448.80	248.80
449.10	249.10
449.12	249.12
449.13	249.13
449.20	249.20
449.31	249.31
449.32	249.32
449.33	249.33
449.40	249.40
449.41	249.41
449.70	249.70
449.81	249.81
449.82	249.82
450.18	250.18
450.19	250.19
450.20	250.20
450.21	250.21
450.23	250.23
450.24	250.24
450.25	250.25
450.30	250.30
450.31	250.31
450.41	250.41
450.70	250.70
450.71	250.71
450.80	250.80
450.90	250.90
450.100	250.100
450.120	250.120
450.210	250.210
450.220	250.220
451.10	251.10
452.10	252.10

Redesignation Table III

The following regulations were reorganized and redesignated at 43 FR 45176, September 29, 1978. For the convenience of the user, the following tables show the relationship of the redesignated sections.

PART 446

Old section	New section
446.10	431.12
446.151	432.2
446.160	432.10
446.165	432.31
446.166	432.32
446.170	432.30
446.175	432.50
446.180	432.55
446.185	432.60

PART 448

Old section	New section
Beginning note	435.2
448.1(a)(1)(i)	435.4
448.1(a)(1)(ii)	435.732
448.1(a)(1)(ii)(A)	435.321
448.1(a)(1)(ii)(B)	435. Unnecessary
448.1(a)(2)(i)	435.4.
448.1(a)(2)(ii)	435.831
448.1(a)(3)	435.740
448.1(b) first sentence	435.10
448.1(b)(1)(i)	435.110
448.1(b)(1)(ii)	435.111
448.1(b)(1)(iii)	435.112
448.1(b)(2)	Unnecessary
448.1(b)(2)(i)	435.120
448.1(b)(2)(ii)	435.230
448.1(b)(2)(iii)	435.121
448.1(b)(2)(iv)	435.130
448.1(b)(2)(v)	435.131
448.1(b)(2)(vi)except (B)	435.132
448.1(b)(2)(vi)(B)	Redundant with 435.132 first sentence
448.1(b)(2)(vii)	435.133
448.1(b)(2)(viii) words before "In States"	Unnecessary
448.1(b)(2)(viii)	435.135
448.1(b)(3) introductory sentence	Unnecessary
448.1(b)(3)(i)	435.113, 435.122
448.1(b)(3)(ii)	435.114, 435.134
448.1(c) first sentence	435.10, 435.200
448.1(c)(1)	435.210
448.1(c)(2) except second sentence	435.211
448.1(c)(2) second sentence	Unnecessary
448.1(c)(3)	435.223
448.1(c)(4)	435.222

PART 448—Continued

Old section	New section
448.1(c)(5)	435.221
448.1(c)(6)	435.220
448.1(d)(1)	435.301
448.1(d)(2)	435.325
448.1(e)	435.10
448.2(a)	435.401
448.2(b)(1)	435.501
448.2(b)(2)	Unnecessary
448.2(c)	435.401
448.2(d)	435.230
448.2(e) words before " . . . if a State plan	Unnecessary
448.2(e) words after "Notwithstanding the provisions specified in paragraph (d) of the section . . ."	435.231, 435.722
448.3(a)(1)	435.10
448.3(a)(1)(i)	435.711
448.3(a)(1)(ii)(A)	435.721(a)
448.3(a)(1)(ii)(B)(*1*)	435.721(a)
448.3(a)(1)(ii)(B)(*2*), words before "provided that"	435.721(b)
448.3(a)(1)(ii)(B)(*2*), words beginning "provided that"	435.1006
448.3(a)(1)(ii)(C), first sentence	435.10
448.3(a)(1)(ii)(C), second sentence	435.121(b)
448.3(a)(2)	Unnecessary
448.3(b)(1)	Unnecessary
448.3(b)(1)(i) first sentence	Unnecessary
448.3(b)(1)(i) second sentence	435.723(b)
448.3(b)(1)(i) third sentence	435.712(a), 435.724(b)
448.3(b)(1)(i) fourth sentence	435.724(b)
448.3(b)(1)(ii)	435.603
448.3(b)(1)(iii)	435.602
448.3(b)(2)(i)	435.723(c)
448.3(b)(2)(ii)	435.723(d)
448.3(b)(2)(iii)	435.721(c)
448.3(b)(2)(iv) first sentence	435.831(a)(2)
448.3(b)(2)(iv) second sentence	Unnecessary
448.3(b)(2)(iv) third sentence words before " . . . after deducting all . . ."	435.811
448.3(b)(2)(iv) third sentence words after " . . . to the assistance unit . . ."	435.831(c)
448.3(b)(3)(i)	435.724(b)
448.3(b)(3)(ii)	435.724(c)
448.3(b)(3)(iii)	435.724(c)
448.3(b)(3)(iv)	435.721(c)

PART 448—Continued

Old section	New section
448.3(b)(3)(v) first sentence words before ". . . except that the income . . .".	435.721(c).
448.3(b)(3)(v) first sentence words after ". . . medically needy determinations . . .".	Unnecessary.
448.3(b)(3)(v) second sentence words before ". . . after deducting all . . .".	435.811.
448.3(b)(3)(v) second sentence words after ". . . to the assistance unit . . .".	435.831(c).
448.3(b)(4) first paragraph	435.734.
448.3(b)(4) second paragraph	Unnecessary.
448.3(b)(5)(i)	435.712(a).
448.3(b)(5)(ii)	435.712(c).
448.3(b)(5)(iii)	435.712(b).
448.3(b)(5)(iv) first sentence	Unnecessary.
448.3(b)(5)(iv) second sentence words before ". . . to the assistance unit . . .".	435.811.
448.3(b)(5)(iv) second sentence words after ". . . to the assistance unit . . .".	435.831(c).
448.3(b)(6)	435.404.
448.3(b)(7)	435.725, 435.731, 435.733, 435.813, 435.815, 435.832.
448.3(b)(8)	435.725, 435.732, 435.733, 435.832.
448.3(b)(9)	435.732.
448.3(c)(1)	Unnecessary.
448.3(c)(1)(i)	435.811.
448.3(c)(1)(ii)	435.812(a), 435.814(a), 435.816(a).
448.3(c)(1)(ii)(A)	435.816.
448.3(c)(1)(ii)(B) words before "except that".	435.812, 435.814.
448.3(c)(1)(ii)(B) words beginning "except that".	Unnecessary.
448.3(c)(1)(iii)	435.812(b), 435.814(b).
448.3(c)(1)(iv) words before "and the amount of liquid . . .".	435.834, 435.835.
448.3(c)(1)(iv) words after ". . . of the Social Security Act . . ." and before ". . . except that . . .".	435.834(c), 435.835(c).
448.3(c)(1)(iv) words after ". . . in a family . . ." to end of sentence.	435.834(b).
448.3(c)(1)(iv) last sentence	Unnecessary.
448.3(c)(2)	435.831.
448.3(c)(3) first sentence	Redundant.
448.3(c)(3)(i)	435.831(a)(1), 435.841(c).
448.3(c)(3)(ii)	435.831(a)(2), (3), 435.841(d), (e).
448.3(c)(4)	435.831(a), 435.841(b).
448.4(a)	435.1001.
448.4(b)(1)	435.1002.
448.4(b)(1)(i)	Unnecessary.
448.4(b)(1)(ii)	Unnecessary.
448.4(b)(1)(iii)	Unnecessary.
448.4(b)(2)	435.1008.
448.4(b)(3) first sentence	435.1005 and 435.1006.
448.4(b)(3) second sentence	Unnecessary.
448.4(b)(4)	435.1007.
448.4(b)(5)	435.1002(b).
448.4(b)(6)	435.1004.
448.4(b)(7) except last sentence	435.1003.
448.4(b)(7) last sentence	Unnecessary.

PART 448—Continued

Old section	New section
448.4(b)(8)	Unnecessary.
448.4(c)	Unnecessary.
448.4(d)	435.1010.
448.4(e)	435.1011.
448.10(a)	Unnecessary.
448.10(b)(1)(i)	436.110.
448.10(b)(1)(ii)	436.115.
448.10(b)(1)(iii)	436.111.
448.10(b)(2)(i)	436.210.
448.10(b)(2)(ii)	436.211.
448.10(b)(2)(iii)	436.212.
448.10(b)(2)(iv)	436.222.
448.10(b)(2)(v)	436.221.
448.10(b)(2)(vi)	436.220.
448.10(b)(3)	436.112.
448.10(b)(4)	436.116.
448.10(b)(5) 1st sentence	436.301, 436.310, 436.320, 436.330.
448.10(b)(5) 2d sentence	Unnecessary.
448.10(b)(6)	436.10.
448.10(b)(7)	Obsolete.
448.10(c)(1)	436.401(b).
448.10(c)(2)	Obsolete.
448.10(c)(3)	436.401(c).
448.10(c)(4)	436.401(a).
448.10(c)(5)	436.602.
448.10(d)(1)	436.1001(a), 436.1002(a).
448.10(d)(2) except undesignated paragraph after.	Unnecessary.
448.10(d)(2) undesignated paragraph after (vi).	436.1004(a).
448.10(d)(3)	436.1002(b).
448.10(d)(4)	436.1003.
448.11	436.230.
448.21(a)(1)(i)	436.711.
448.21(a)(1)(ii)	Redundant.
448.21(a)(2)(i)(A)–(C) 1st sentence except words before "and amounts received".	Redundant.
448.21(a)(2)(i)(C) 1st sentence, words after "applicant or recipient", and 2d sentence.	436.603.
448.21(a)(2)(ii)	436.602.
448.21(a)(2)(iii)	Redundant.
448.21(a)(2)(iv)	436.711.
448.21(a)(2)(v)	436.711.
448.21(a)(2)(vi)	436.404.
448.21(a)(3)(i) introductory paragraph.	Unnecessary.
448.21(a)(3)(i)(A)	436.811.
448.21(a)(3)(i)(B)	436.812.
448.21(a)(3)(i)(C) 1st and 2d sentences.	436.813.
448.21(a)(3)(i)(C) 3d–4th sentences.	436.832.
448.21(a)(3)(i)(D) 1st sentence	436.840.
448.21(a)(3)(i)(D) last sentence	Unnecessary.
448.21(a)(1)(ii)–(iv)	436.831.
448.21(b)	Redundant.
448.21(c)	436.1002.
448.30(a), (b)(2) and (3)	435.520, 436.520.
448.30(b)(1) 1st sentence	Redundant with 435.1002.
448.30(b)(1) 2d sentence	Unnecessary.
448.40(a)(1) words before "but are absent", and (b)(1) and (2).	435.403, 436.403.
448.40(a) words after "residents of the State".	431.52.
448.40(b) introductory paragraph	Redundant with 435.403(a).

PART 448—Continued

Old section	New section
448.50	435.402, 436.402.
448.60(a)(1)–(3)(i) and (iv)	435.1008, 436.1004.
448.60(a)(3)(ii) except "or mental diseases".	435.1009 "institution for tuberculosis".
448.60(a)(3)(ii) except "tuberculosis or".	435.1009 "institution for mental diseases".
448.60(a)(3)(iii)	435.1009 "institution for mental diseases".
448.60(b)(1)–(11)	435.1009, 436.1005.
448.70(a)(1) words before "and in Guam".	435.530.
448.70(a)(1) words after parenthetical note.	436.530.
448.70(a)(2)(i) and (ii) 1st sentence.	435.531(a)(1) and (2), 436.531(a) and (b).
448.70(a)(2)(ii) 2d sentence	435.531(a)(3), 436.531(c).
448.70(a)(3)	435.531(a)(3), 436.531(c).
448.70(b)	435.531(b).
448.70(c)(1) 1st sentence	Redundant with 435.1002.
448.70(c)(1) 2d sentence	435.531(a)(3)(ii).
448.70(c)(1) parenthetical note	435.1003.
448.70(c)(2)	435.1001(b), 436.1001(b).
448.80(a)(1) words before "and in Guam".	435.540.
448.80(a)(1) words after parenthetical note.	436.540.
448.80(a)(2) and (b)	435.541, 436.541.
448.80(c)(1) 1st sentence	Redundant with 435.1002.
448.80(c)(1) 2d sentence	435.541(c).
448.80(c)(2)	435.1001(b), 436.1001(b).

PART 449

Old section	New section
449.10(a)(1)	440.210.
449.10(a)(2)	440.220.
449.10(a)(3) introductory paragraph.	441.51.
449.10(a)(3)(i)	441.54.
449.10(a)(3)(ii)	441.55.
449.10(a)(3)(iii)	441.56.
449.10(a)(3)(iv)	441.53.
449.10(a)(4)	441.15.
449.10(a)(5)(i)	440.230.
449.10(a)(5)(ii)	431.53.
449.10(a)(6) introductory paragraph.	440.240.
449.10(a)(6)(i)–(vii)	440.250.
449.10(a)(7)	440.240.
449.10(a)(8)	440.260.
449.10(a)(9)	441.20.
449.10(a)(10)	441.30.
449.10(a)(11)	431.110, 442.201(c), 442.251(d).
449.10(b) introductory paragraph	440.2.
449.10(b)(1)	440.10.
449.10(b)(2)	440.20.
449.10(b)(3)	440.30.
449.10(b)(4)(i)(A)	440.40.
449.10(b)(4)(i)(B)	442.201(a), (b).
449.10(b)(4)(i)(C) 1st sentence, words before "except that with".	440.40.

PART 449—Continued

Old section	New section
449.10(b)(4)(i)(C) 1st sentence, words after "payments under the plan".	441.11.
449.10(b)(4)(i)(C) 2d and 3d sentences.	442.30.
449.10(b)(4)(ii) 1st sentence	440.40.
449.10(b)(4)(ii) 2d and 3d sentences.	441.52.
449.10(b)(5)	440.50.
449.10(b)(6)	440.60.
449.10(b)(7) except (i) introductory paragraph, last sentence.	440.70.
449.10(b)(7)(i) introductory paragraph, last sentence.	Redundant.
449.10(b)(8)	440.80.
449.10(b)(9)	440.90.
449.10(b)(10)	440.100.
449.10(b)(11)	440.110.
449.10(b)(12)	440.120.
449.10(b)(13)	440.130.
449.10(b)(14)	440.140.
449.10(b)(15)(i)(A) 1st sentence	440.150.
449.10(b)(15)(i)(A) last sentence	442.251(a), (c), 442.252.
449.10(b)(15)(i)(B)	440.150.
449.10(b)(15)(i)(C)	442.252.
449.10(b)(15)(i)(D)	Redundant.
449.10(b)(15)(i)(E)	440.150.
449.10(b)(15)(ii)	442.254.
449.10(b)(15)(iii)	440.150.
449.10(b)(15)(iv)	440.150.
449.10(b)(15)(v)	Redundant.
449.10(b)(15) undesignated paragraph after (v).	441.11.
449.10(b)(15)(vi)	442.30.
449.10(b)(16) introductory paragraph.	440.160.
449.10(b)(16)(i), (ii)	441.151.
449.10(b)(16)(iii) introductory paragraph.	441.152.
449.10(b)(16)(iii)(A) words before "and for whom".	Obsolete.
449.10(b)(16)(iii)(A) words after "of these regulations".	441.153.
449.10(b)(16)(iii)(B)	Obsolete.
449.10(b)(16)(iii)(C)–(E)	441.153.
449.10(b)(16)(iv)(A), except 2d sentence.	441.154.
449.10(b)(16)(iv)(A) 2d sentence	Redundant.
449.10(b)(16)(iv)(B)	441.155.
449.10(b)(16)(iv)(C)	441.156.
449.10(b)(17)	440.170.
449.10(c)(1) and (2)	441.13.
449.10(c)(3)	Surplusage.
449.10(c)(4)	441.40.
449.10(c)(5) except (ii)(A)–(G)	441.182.
449.10(c)(5)(ii)(A)–(G)	441.181.
449.10(d)(1)(i)	435.1009, 440.2.
449.10(d)(1)(ii), (iv)–(vi)	435.1009.
449.10(d)(1)(iii)	440.2.
449.10(d)(2)	440.270.
449.10(d)(3)	441.11.
449.12(a) introductory paragraph	442.300.
449.12(a)(1)	442.301.
449.12(a)(1)(i) 1st sentence	442.302.
449.12(a)(1)(i) 2d sentence	Unnecessary.
449.12(a)(1)(ii)(A)	442.305.
449.12(a)(1)(ii)(A)(*1*)(*i*)	442.306.
449.12(a)(1)(ii)(A)(*1*)(*ii*), (*iii*)	442.307.
449.12(a)(1)(ii)(A)(*2*)	442.308.
449.12(a)(1)(ii)(A)(*3*)	442.309.

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Old section	New section
449.12(a)(1)(ii)(A)(4)	442.310.
449.12(a)(1)(ii)(B)	442.311, 442.404.
449.12(a)(1)(ii)(C)	442.312, 442.405.
449.12(a)(1)(iii)	442.320, 442.406(d), (e).
449.12(a)(1)(iv), (v)	442.313.
449.12(a)(1)(vi)	442.314.
449.12(a)(1)(vii)	442.315, 442.415.
449.12(a)(2)	442.316, 442.425(a), (b).
449.12(a)(3)	442.317, 442.417, 442.476(c).
449.12(a)(4)(i)(A)-(E)	442.318(a)-(c), 442.319.
449.12(a)(4)(i)(F)	Obsolete.
449.12(a)(4)(ii), (iii)	442.318(d), (e).
449.12(a)(5) introductory paragraph.	442.321(a), 442.507(a).
449.12(a)(5)(i)	442.322, 442.508.
449.12(a)(5)(ii)	442.323(a), 442.509(a).
449.12(a)(5)(iii)	442.321(b), 442.507(b).
449.12(a)(5) undesignated paragraph following paragraph (iii).	442.323(b), 442.509(b).
449.12(a)(6)(i)	442.324(a), 442.325, 442.326(a), 442.446, 442.447(a)(1), (3), 442.448(a), (d).
449.12(a)(6)(ii)	442.327.
449.12(a)(6)(iii)	442.326(b), (c).
449.12(a)(6)(iv)	442.324(b).
449.12(a)(6)(v), (vi)	442.328.
449.12(a)(6)(vii), (viii)	442.329.
449.12(a)(6)(ix)	442.330, 442.511.
449.12(a)(7)(i)	442.331(a).
449.12(a)(7)(ii)-(iv)	442.332.
449.12(a)(7)(vi), (vii)	442.331(b).
449.12(a)(8)(i)	442.333.
449.12(a)(8)(ii)	442.334.
449.12(a)(8)(iii)	442.335.
449.12(a)(8)(iv)	442.337(b).
449.12(a)(8)(v)	442.336.
449.12(a)(8)(vi)	442.337(a).
449.12(a)(9) introductory paragraph.	442.338, 442.474(b).
449.12(a)(9)(i) and (A)-(C)	442.339, 442.481(a)-(e).
449.12(a)(9)(ii)	442.340, 442.481(f).
449.12(a)(9)(iii)	442.481(g).
449.12(a)(9)(iv)	442.341, 442.481(h).
449.12(a)(9)(v)	442.342, 442.478(a).
449.12(b) introductory paragraph	Unnecessary.
449.12(b)(1)	442.303.
449.12(b)(2)	442.304.
449.12(b)(3)	442.343.
449.12(b)(4)	442.344.
449.12(b)(5)	442.345.
449.12(b)(6)	442.346.
449.12(c) introductory paragraph	442.400.
449.12(c)(1)	442.418(a), (b).
449.12(c)(2)	442.410(a), (b).
449.12(c)(3) introductory paragraph, 1st sentence.	442.411.
449.12(c)(3) introductory paragraph, 2d sentence, and (i)-(ix).	442.401.
449.12(c)(4)-(6)	Obsolete.
449.13 introductory paragraph, 1st sentence, words before "the standards for".	Obsolete.
449.13 introductory paragraph, 1st sentence, words after "July 18, 1977".	442.400.
449.13 introductory paragraph 2d sentence.	Obsolete.

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Old section	New section
449.13(a)(1)(i)	442.402.
449.13(a)(1)(ii)	442.403.
449.13(a)(1)(iii)	442.406(a)-(c).
449.13(a)(1)(iv)	442.407.
449.13(a)(1)(v)	442.408.
449.13(a)(1)(vi)	442.409(a)(1), (2).
449.13(a)(1)(vii)	442.409(a)(3).
449.13(a)(1)(viii)	442.410(a)(2).
449.13(a)(1)(ix)	442.412.
449.13(a)(1)(x)	442.413.
449.13(a)(1)(xi)	442.414.
449.13(a)(2)(i) introductory paragraph, 1st sentence	442.418(a).
449.13(a)(2)(i) introductory paragraph, 2d sentence, and (A) and (B).	442.420.
449.13(a)(2)(ii)	442.419.
449.13(a)(2)(iii)	442.418(a), (b)(1).
449.13(a)(2)(iv)	442.418(b)(2), (c).
449.13(a)(2)(v)	442.421.
449.13(a)(2)(vi)	442.422.
449.13(a)(2)(vii)	442.423.
449.13(a)(2)(viii)	442.424(c), 442.425(c).
449.13(a)(2)(ix)	442.424(a), (b).
449.13(a)(2)(x)	442.425(c).
449.13(a)(2)(xi), (xii)	442.426.
449.13(a)(3)(i)	Unnecessary.
449.13(a)(3)(ii)	442.427(b).
449.13(a)(3)(iii), (iv)	442.428.
449.13(a)(3)(v)	442.429.
449.13(a)(3)(vi)	442.427(a).
449.13(a)(3)(vii)	442.430.
449.13(a)(3)(viii)	442.431.
449.13(a)(3)(ix), (x)	442.432.
449.13(a)(3)(xi)	442.427(c).
449.13(b)(1)(i), (ii)	442.433.
449.13(b)(1)(iii)	442.434.
449.13(b)(1)(iv)-(vi)	442.435.
449.13(b)(1)(vii)	442.436.
449.13(b)(1)(viii)-(x)	442.437.
449.13(b)(1)(xi) introductory paragraph and (A)-(C).	442.438(a)-(e).
449.13(b)(1)(xi)(D) 1st sentence	442.439(a).
449.13(b)(1)(xi)(D) 2d sentence	442.438(f).
449.13(b)(1)(xi)(E)	442.439(b), (c).
449.13(b)(1)(xii)	442.440.
449.13(b)(1)(xiii)	442.441(b)-(d).
449.13(b)(2)	442.442.
449.13(b)(3)	442.443.
449.13(b)(4)	442.444.
449.13(b)(5)	442.445.
449.13(b)(6)(i)	442.447(a)(1), (2), (4), (5), (b), (c).
449.13(b)(6)(ii)	442.448.
449.13(b)(6)(iii), (iv)	442.449(a), (b).
449.13(b)(6)(v), (vi)	442.450(a)(2), (3).
449.13(b)(6)(vii), (viii)	442.451(a).
449.13(b)(6)(ix)	442.452.
449.13(b)(6)(x)	442.451(b).
449.13(b)(6)(xi)	442.450(a)(4), (b), (c).
449.13(b)(6)(xii)	442.453.
449.13(b)(6)(xiii)	442.449(c).
449.13(c)(1)	442.454.
449.13(c)(1)(i)	442.455.
449.13(c)(1)(ii)	442.456.
449.13(c)(2)(i)	442.457.
449.13(c)(2)(ii)	442.458.
449.13(c)(2)(iii)	442.459.
449.13(c)(2)(iv)	442.460.
449.13(c)(2)(v)	442.461.

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Old section	New section
449.13(c)(2)(vi)	442.462
449.13(c)(3)(i)	442.401, 442.463(a)
449.13(c)(3)(ii)–(v)	442.463(b)–(e)
449.13(c)(3)(vi)	442.411(a), 442.464
449.13(c)(4)(i)	442.465
449.13(c)(4)(ii), (iii)	442.466(a)–(c)
449.13(c)(4)(iv) introductory paragraph, 1st sentence	442.466(d)
449.13(c)(4)(iv) introductory paragraph, 2d sentence, and (A)–(C)	442.467(a)
449.13(c)(4)(v)	442.468
449.13(c)(4)(vi)	442.467(b)
449.13(c)(4)(vii) 1st and 2d sentences	442.469
449.13(c)(4)(vii) 3d sentence	442.467(c)
449.13(c)(4)(vii) 4th and 5th sentences	442.470
449.13(c)(4)(viii), (ix)	442.471
449.13(c)(4)(x), (xi)	442.472
449.13(c)(4)(xii)–(xiv)	442.473
449.13(c)(5)(i), (ii)	442.474(a), (c), (e)
449.13(c)(5)(iii), (iv)	442.475
449.13(c)(5)(v)	442.477
449.13(c)(5)(vi), (vii)	442.476
449.13(c)(5)(viii)	442.474(d)
449.13(c)(6)(i), (ii)	442.478
449.13(c)(6)(iii)	442.479
449.13(c)(6)(iv), (v)	442.480
449.13(c)(7)(i) 1st sentence	442.483(a)
449.13(c)(7)(i) 2d sentence, (ii), (iii)	442.482
449.13(c)(7)(iv)–(vi)	442.483(b)–(d)
449.13(c)(7)(vii)	442.484(a)
449.13(c)(7)(viii)	442.485
449.13(c)(7)(ix)–(xi)	442.484(b)–(d)
449.13(c)(8)(i)–(iii)	442.486
449.13(c)(8)(iv)	442.487
449.13(c)(8)(v), (vi)	442.488
449.13(c)(9)(i)	442.489(a)
449.13(c)(9)(ii)–(iv)	442.490(b)–(d)
449.13(c)(9)(v)	442.489(b)
449.13(c)(9)(vi)	442.490(a)
449.13(c)(10)(i)	442.491(a)
449.13(c)(10)(ii)	442.492
449.13(c)(10)(iii), (iv)	442.493
449.13(c)(10)(v), (vi)	442.491(b), (c)
449.13(c)(11)(i)	442.494
449.13(c)(11)(ii)–(vi)	442.495
449.13(c)(12)(i), (ii)	442.496
449.13(c)(12)(iii), (iv)	442.497
449.13(c)(12)(v), (vi)	442.498
449.13(d)(1)(i)–(iii)	442.499
449.13(d)(2)(i)	442.500
449.13(d)(2)(ii), (iii)	442.501(a), (b)
449.13(d)(2)(iv)	442.424(c), 442.501(c)
449.13(d)(3)	442.502
449.13(d)(4)	442.503
449.13(d)(5)	442.504
449.13(e)	442.416
449.13(f)(1)(i)	442.505
449.13(f)(1)(ii), (iii)	442.506
449.13(f)(1)(iv)	442.511
449.13(f)(1)(v)	442.510
449.13(f)(2)	442.512
449.13(g)(1)	442.513
449.13(g)(2)	442.514
449.13(g)(3)	442.515
449.13(g)(4)	442.516
449.13(h)(1)	442.401
449.13(h)(2)	442.409(a)(4); 442.410(a)(1), (c)
449.13(h)(3)	Unnecessary
449.13(h)(4)	442.409(a)(1), (2), (b)
449.13(h)(5)–(9)	442.401
449.13(h)(10)	442.441(a)
449.20	431.51
449.31	447.10
449.32	447.25
449.33(a) introductory paragraph	442.10, 442.100
449.33(a)(1) introductory paragraph except words "(including hospitals)"	442.12(a), 442.101
449.33(a)(1) introductory paragraph words "(including hospitals)"	Unnecessary
449.33(a)(1)(i) words before "that the facility meets"	442.101(b)
449.33(a)(1)(i) words after "this chapter"	442.101(d), 442.200, 442.202, 442.253
449.33(a)(1)(ii) words before "and in the case", except words "pursuant to section 1910 of the Act"	442.101(b)(2)
449.33(a)(1)(ii) words "pursuant to sec. 1910 of the Act"	442.1(a)(7)
449.33(a)(1)(ii) words after "title XVIII of the act"	442.202(c)(3)
449.33(a)(1)(iii) words before "except that", except words "pursuant to sec. 1905 of the Act"	442.101(b)(1), 442.200, 442.202(b), (c)
449.33(a)(1)(iii) words "pursuant to sec. 1905 of the Act"	442.1(a)(6)
449.33(a)(2) introductory paragraph except words "(including hospitals and skilled nursing facilities)"	442.12(a), 442.101(a), 442.250
449.33(a)(2) introductory paragraph words "(including hospital and skilled nursing facilities)"	Unnecessary
449.33(a)(2)(i) except words "in accordance with paragraph (a)(4)(iii) of this section" and paragraph (E)	442.112
449.33(a)(2)(i) words "in accordance with paragraph (a)(4)(iii) of this section"	Redundant
449.33(a)(2)(i)(E)	Redundant
449.33(a)(2)(ii) except words "in accordance with paragraph (a)(4)(iii)(A) of this section" and paragraphs (A)(*2*) and (*3*) and (D)	442.113
449.33(a)(2)(ii) words "in accordance with paragraph (a)(4)(iii)(A) of this section"	Redundant
449.33(a)(2)(ii)(A)(*2*)	Obsolete
449.33(a)(2)(ii)(A)(*3*)	442.115
449.33(a)(2)(ii)(D)	Redundant
449.33(a)(3)	455.104
449.33(a)(4)(i) and (ii) introductory paragraph	442.100, 442.101(d)
449.33(a)(4)(ii)	442.105
449.33(a)(4)(iii) except last sentence	442.111
449.33(a)(4)(iii) last sentence	442.110(a), 442.111(a)
449.33(a)(4)(iv)(A), (B)(*1*)	442.105(c), (d)
449.33(a)(4)(iv)(B)(*2*)	Obsolete

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Old section	New section
449.33(a)(4)(v)	442.101(e).
449.33(a)(5)	431.610(h).
449.33(a)(6) 1st sentence	442.12(a).
449.33(a)(6) 2d sentence, words before "and the effective date".	442.15(a).
449.33(a)(6) 2d sentence, words after "of one year".	442.12(b).
449.33(a)(6) 3d sentence, words before "except that".	442.12(c), 442.15(b).
449.33(a)(6) 3d sentence, words after "by the survey agency" and before "or may elect".	442.15(b).
449.33(a)(6) 3d sentence, words after "period of certification".	442.12(d).
449.33(a)(6) 4th sentence	442.16.
449.33(a)(7), (8)	Surplusage.
449.33(a)(9)	442.20.
449.33(a)(10)	Redundant.
449.33(b)(1)	Redundant.
449.33(b)(2)	431.610(i).
449.40(a)(1) words before "and no reduction".	447.51.
449.40(a)(1) words after "under the plan".	447.53.
449.40(a)(2)	447.51.
449.40(a)(2)(i), (ii)	447.52.
449.40(a)(3) 1st and 2d sentences.	447.53.
449.40(a)(3)(i), (ii)	447.54.
449.40(a)(3)(iii)	447.55.
449.40(a)(3)(iv)	447.54.
449.40(a)(3)(v)	447.56.
449.40(a)(3)(vi) 1st sentence	447.57.
449.40(a)(3)(vi) 2d sentence	447.58.
449.40(b)	447.59.
449.41	431.625.
449.70	433.36.
449.82(a)	431.501.
449.82(b)(1)-(7)	431.502.
449.82(b)(8)	431.521.
449.82(b)(9)-(11)	431.502.
449.82(c)(1)(i)-(ix)	431.503.
449.82(c)(1)(x)	431.504.
449.82(c)(2)	431.512.
449.82(c)(3)	431.510.
449.82(c)(4)	431.511.
449.82(c)(5) introductory paragraph words before "a State plan for".	431.523-431.526, 431.557-431.560.
449.82(c)(5) introductory paragraph words after "and (2) of this section" and (i).	431.527.
449.82(c)(5) introductory paragraph words after "and (2) of this section", and (i) 1st sentence.	431.568.
449.82(c)(5)(ii)	431.528, 431.569.
449.82(c)(5)(iii)	Redundant.
449.82(c)(5)(iv)	431.527, 431.568.
449.82(c)(5)(v) words before "which shall be".	431.529, 431.570.
449.82(c)(5)(v) words after "period of enrollment".	431.541, 431.581.
449.82(c)(5)(vi)	431.530, 431.571.
449.82(c)(5)(vii)	431.531, 431.572.
449.82(c)(5)(viii), (ix)	431.532, 431.573.
449.82(c)(5)(x)	431.533, 431.574.
449.82(c)(5)(xi)	431.534, 431.575.
449.82(c)(5)(xii)	431.535, 431.576.
449.82(c)(5)(xiii)	431.536, 431.577.
449.82(c)(5)(xiv)	431.537, 431.578.
449.82(c)(5)(xv)	431.565.
449.82(c)(5)(xvi)	431.522.
449.82(c)(6)(i)	431.540, 431.580.
449.82(c)(6)(ii)	431.541, 431.581.
449.83(c)(6)(iii)	431.542, 431.582.
449.82(c)(6)(iv)	431.543, 431.583.
449.82(c)(6)(v)	431.544, 431.584.
449.82(c)(6)(vi)	431.545, 431.585.
449.82(c)(6)(vii)	431.546, 431.586.
449.82(c)(6)(viii)	431.547.
449.82(c)(6)(ix)	431.548, 431.587.
449.82(c)(6)(x)	431.549, 431.588.
449.82(c)(6)(xi)	431.550, 431.589.
449.82(d)(1)	431.591.
449.82(d)(2)	431.592.
449.82(d)(3)	431.593.
449.82(d)(4)(i), (ii)	431.597.
449.82(d)(4)(iii)	431.594.
449.82(d)(4)(iv)	431.595.
449.82(d)(4)(v)	431.596.
449.100	Unnecessary.
449.101	441.201.
449.102	441.202.
449.103	441.203.
449.104	441.204.
449.105	441.205.
449.106	441.206.
449.107	441.207.
449.108	441.208.
449.109	Redundant with 45 CFR 205.50.

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Old section	New section
450.18 introductory paragraph	456.2.
450.18(a) introductory paragraph	456.3.
450.18(a)(1) introductory paragraph	Unnecessary.
450.18(a)(1)(i)	456.22.
450.18(a)(1)(ii)	456.23.
450.18(a)(1)(iii)	456.3.
450.18(a)(1)(iv)	456.346, 456.347, 456.348.
450.18(a)(1)(v) except last sentence	Unnecessary.
450.18(a)(1)(v) last sentence	456.171, 456.271, 456.372.
450.18(a)(2)	456.60, 456.160, 456.260, 456.360.
450.18(a)(3)(i) and (iii)	456.80.
450.18(a)(3)(ii)	456.80, 456.180, 456.280, 456.380.
450.18(a)(3)(iv)	456.280, 456.281.
450.18(a)(4)	456.3.
450.18(a)(5)	456.3.
450.18(b)	456.4.
450.18(c)	456.5.
450.18(d) words before "and will perform".	456.6.
450.18(d) words after "of this chapter".	Redundant.
450.18(e)	Redundant.
450.18(f)	Obsolete.

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Old section	New section
450.19(a) introductory paragraph first two words after caption and words after "intermediate care facility"	456.101
450.19(a) first word, "mental Hospital," and words after "intermediate care facility" and before "which meets"	456.201(a)
450.19(a) first word and words after "mental hospital" except "and intermediate care"	456.301
450.19(a) first word, words after "skilled nursing facility and" and 450.19(a)(4) introductory paragraph words after "Christian Science Sanatoriums"	456.401
450.19(a) introductory paragraph words after "* * * review plan * * *"	456.201(b)
450.19(a)(1) introductory paragraph	456.102
450.19(a)(1)(i)	456.113
450.19(a)(1)(ii) introductory paragraph	456.105
450.19(a)(1)(ii)	456.106
450.19(a)(1)(iii)(A)	456.129
450.18(a)(1)(iii)(B)	456.142
450.19(a)(1)(iii)(C)	456.129 and 456.134
450.19(a)(1)(iv)	456.129 and 456.134
450.19(a)(1)(v)	456.105
450.19(a)(1)(vi)	456.112
450.19(a)(1)(vii)	456.111
450.19(a)(1)(viii) introductory paragraph words before "within one working day"	456.121
450.19(a)(1)(viii) introductory paragraph words before "by the committee" except parenthetical note	456.125
450.19(a)(1)(viii) parenthetical note	456.127
450.19(a)(1)(viii) introductory paragraph words after "of such application"	456.123
450.19(a)(1)(viii)(A)	456.126
450.19(a)(1)(viii)(B) 1st and 2d sentences except words after "criteria and" and before "are applied"	456.122
450.19(a)(1)(viii)(B) 1st and 2d sentences	456.123
450.19(a)(1)(viii)(B) 3d sentence	Obsolete
450.19(a)(1)(viii)(C), (D), (E) words before "and written notification" and (F) words before "written notification thereof"	456.123
450.19(a)(1)(viii)(E) words after "shall be considered final" and (F) words after "is not necessary"	456.124
450.19(a)(1)(ix)	456.128
450.19(a)(1)(ix) words before "and recorded"	456.123
450.19(a)(1)(ix) words after "shall be assigned" and before "based on the patient's"	456.111
450.19(a)(1)(x) words before "by the Group"	456.135

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Old section	New section
450.19(a)(1)(x) introductory paragraph	456.135
450.19(a)(1)(x)(A)	456.137
450.19(a)(1)(x)(B)	456.135
450.19(a)(1)(x)(C) 1st and 2d sentences except words after "criteria and" and before "are applied"	456.132
450.19(a)(1)(x)(C) 1st and 2d sentences	456.135
450.19(a)(1)(x)(C) 3d sentence	Obsolete
450.19(a)(1)(x)(D) words before "in accordance with"	456.135
450.19(a)(1)(x)(D) words after "shall be determined"	456.133
450.19(a)(1)(x)(E), (F), (G) words before "and written notification" and (H) words before "written notification"	456.135
450.19(a)(1)(x)(G) words after "shall be considered final" and (H) words after "has not been justified"	456.136
450.19(a)(1)(xi)(A) first 2 sentences	456.141
450.19(a)(1)(xi)(A) 3d and 4th sentences	456.143
450.19(a)(1)(xi)(A) 5th sentence	456.145
450.19(a)(1)(xi)(A) 6th sentence	456.144
450.19(a)(1)(xi)(B)	456.142
450.19(a)(1)(xii)	456.142
450.19(a)(2) introductory paragraph	456.201(b)
450.19(a)(2)(i)	456.213
450.19(a)(2)(ii) introductory paragraph	456.205 (a) and (b)
450.19(a)(2)(ii)(A)	456.206(b)
450.19(a)(2)(ii)(B)	456.206(c)
450.19(a)(2)(iii)(A)	456.242(a)
450.19(a)(2)(iii)(B)	456.235(b)
450.19(a)(2)(iv)	456.235(a)
450.19(a)(2)(v)	456.205(c)
450.19(a)(2)(vi)	456.212
450.19(a)(2)(vii)	456.211
450.19(a)(2)(viii) words before "on or before a specified date"	456.231
450.19(a)(2)(viii) words after "necessity of continued stay" and before 7th sentence	456.233
450.19(a)(2)(viii) 7th sentence	456.234(b)
450.19(a)(2)(viii) 8th sentence	456.211(e)
450.19(a)(2)(ix) introductory paragraph	456.236(a)
450.19(a)(2)(ix)(A)	456.238
450.19(a)(2)(ix)(B)	456.236(c)
450.19(a)(2)(ix)(C) 1st sentence	456.232(a), 456.236(c)
450.19(a)(2)(ix)(C) 2d sentence	456.232(b), 456.236(c)
450.19(a)(2)(ix)(C) 3d sentence	Obsolete
450.19(a)(2)(ix)(D) words before "in accordance with"	456.236(d)
450.19(a)(2)(ix)(D) first sentence words after "is appropriate and"	456.211(e)
450.19(a)(2)(ix)(D) words after "date assigned"	456.234 (a) and (c)
450.19(a)(2)(ix)(D) second sentence words before "in like manner"	456.236(b)
450.19(a)(2)(ix)(E)	456.236(e)

PART 450—Continued

Old section	New section
450.19(a)(2)(ix)(F)	456.236(f).
450.19(a)(2)(ix)(G) words before "and written notification".	456.236(g).
450.19(a)(2)(ix)(G) words after "considered final".	456.237.
450.19(a)(2)(ix)(H) words before "written notification".	456.236(h).
450.19(a)(2)(ix)(H) words after "mental hospital services".	456.237.
450.19(a)(2)(x) introductory words.	456.242(b).
450.19(a)(2)(x)(A) 1st sentence	456.241(a).
450.19(a)(2)(x)(A) 2d sentence	456.241.
450.19(a)(2)(x)(A) 3d and 4th sentences.	456.243.
450.19(a)(2)(x)(A) 5th sentence	456.245.
450.19(a)(2)(x)(A) last sentence	456.244.
450.19(a)(2)(x)(B)	456.242(b).
450.19(a)(2)(xi)	456.242(b).
450.19(a)(3) introductory paragraph.	456.302.
450.19(a)(3)(i)	456.313.
450.19(a)(3)(ii) introductory paragraph.	456.305 (a) and (b).
450.19(a)(3)(ii)(A)	456.306(b).
450.19(a)(3)(ii)(B)	456.306(c).
450.19(a)(3)(iii)(A)	456.342(a).
450.19(a)(3)(iii)(B)	456.335.
450.19(a)(3)(iv)	456.335.
450.19(a)(3)(v)	456.305(c).
450.19(a)(3)(vi)	456.312.
450.19(a)(3)(vii)	456.311.
450.19(a)(3)(viii) words before "on or before a specified date".	456.331.
450.19(a)(3)(viii) introductory paragraph.	456.333.
450.19(a)(3)(viii) introductory paragraph 2d sentence words before "is either".	456.311(e).
450.19(a)(3)(viii)(A) words before "but at least".	456.333.
450.19(a)(3)(viii)(A) words after "functional capabilities".	456.334(b).
450.19(a)(3)(viii)(B) words after "first 90 days".	456.334(b).
450.19(a)(3)(ix) introductory paragraph, (A) and (B) 1st and 2d sentences.	456.336 (a) and (c).
450.19(a)(3)(ix)(B) 2d sentence except words "and closer professional scrutiny".	456.332.
450.19(a)(3)(ix)(B) 3d and 4th sentence.	Obsolete.
450.19(a)(3)(ix)(C) words before "in accordance with".	456.336(d).
450.19(a)(3)(ix)(C) words after "date assigned".	456.334 (a) and (c).
450.19(a)(3)(ix)(C) after "is appropriate" and before "At the expiration".	456.311(e).
450.19(a)(3)(ix) last sentence words before "in like manner".	456.336(b).
450.19(a)(3)(ix)(D)	456.336(e).
450.19(a)(3)(ix)(E)	456.336(f).
450.19(a)(3)(ix)(F) words before "and written notification" and (G) words before "written notification".	456.336 (g) and (h).
450.19(a)(3)(ix)(F) words after "shall be considered final" and before "not later than" and words after "the assigned review date"; and (G) words after "nursing facility services" and before "not later than" and words after "assigned review date".	456.337.
450.19(a)(3)(ix)(F) words after "shall be sent" except (1)-(4) and (G) words after "shall be made" except (1)-(4).	456.388.
450.19(a)(3)(x)(A) 1st and 2d sentences.	456.341.
450.19(a)(3)(x)(A) 3d and 4th sentences.	456.343.
450.19(a)(3)(x)(A) 5th sentence	456.345.
450.19(a)(3)(x)(A) 6th sentence	456.344.
450.19(a)(3)(x)(B)	456.342(b).
450.19(a)(3)(xi)	456.342(b).
450.19(a)(4) introductory paragraph parenthetical note.	456.351.
450.19(a)(4) 2d and 3d sentences except (i)-(vii).	456.401.
450.19(a)(4)(i)	456.413.
450.19(a)(4)(ii) 1st sentence except "and by whom".	456.405.
450.19(a)(4)(ii)(A) words after "How, when and".	456.406.
450.19(a)(4)(ii)(B)	456.407.
450.19(a)(4)(iii)	456.435.
450.19(a)(4)(iv)	456.412.
450.19(a)(4)(v)	456.411.
450.19(a)(4)(vi) words before "or more frequently" and words after "at the time of assessment".	456.431.
450.19(a)(4)(vi) 1st sentence words after "for continued stay".	456.433, 456.434.
450.19(a)(4)(vii) introductory paragraph.	456.436.
450.19(a)(4)(vii)(A)	456.436.
450.19(a)(4)(vii)(B)	456.436.
450.19(a)(4)(vii)(B) 2d sentence except words "and closer professional scrutiny".	456.432.
450.19(a)(4)(vii)(C) words before "in accordance with".	456.436, 456.411(e).
450.19(a)(4)(vii)(C) words after "date assigned".	456.434.
450.19(a)(4)(vii)(C) 2d sentence words before "in like manner".	456.436.
450.19(a)(4)(vii)(D)	456.436.
450.19(a)(4)(vii)(E)	456.436.
450.19(a)(4)(vii)(F) words before "and written notification" and (G) words before "written notification".	456.436.
450.19(a)(4)(vii)(F) words after "shall be considered final" to words before "to: (1)" and (G) words after "intermediate care facility services" to words before "to (1)".	456.438.

PART 450—Continued

Old section	New section
450.19(a)(4)(vii)(F) words after "shall be considered final" to words before "not later than" and words after "final determination"; and (G) words after "intermediate care facility services" and before "not later than" and words after "such final determination".	456.437.
450.19(b) 1st sentence	456.505.
450.19(b) 2d sentence	456.507.
450.19(b) 3d sentence	456.507.
450.19(b) 4th sentence	456.508
450.19(b) 5th sentence	Redundant.
450.19(b) 6th sentence	456.506.
450.19(b) 7th sentence	456.506.
450.19(b) 8th sentence	456.506.
450.19(c)(1)(i)	456.520.
450.19(c)(1)(ii)	Redundant.
450.19(c)(2)	456.521(a)(1).
450.19(c)(3)	456.522(i).
450.19(c)(4)	456.522(j).
450.19(c)(5) 1st sentence	456.521(a)(2).
450.19(c)(5) 2d sentence	456.523(a).
450.19(c)(6)	456.521(b).
450.19(c)(7)	456.522.
450.19(c)(7)(i)	456.522(a).
450.19(c)(7)(ii)	456.522(b).
450.19(c)(7)(iii)	456.522(c).
450.19(c)(7)(iv)	456.522(g).
450.19(c)(7)(v)	456.522(d).
450.19(c)(7)(vi)	456.522(e).
450.19(c)(7)(vii)	456.522(h).
450.19(c)(7)(viii)	456.522(f).
450.19(c)(7)(ix)	456.522(k).
450.19(c)(8) 1st sentence words before "upon receipt" and after "of this section,"	456.524(b).
450.19(c)(8) words after "agency shall," and before "promptly notify".	456.524(a)(1).
450.19(c)(8) 2d sentence	456.523(b).
450.19(c)(9) 1st sentence	456.524(a)(2).
450.19(c)(9) 2d sentence	456.525.
450.19(c)(9) 3d sentence	456.525.
450.20(a)	Redundant.
450.20(b)	Obsolete.
450.20(c) 1st sentence	456.501.
450.20(c) 2d, 3d, and 4th sentences.	456.506.
450.21	431.107.
450.23(a)	456.2.
450.23(a)(1) 1st and 2d sentences.	456.170, 456.180, 456.270, 456.280.
450.23(a)(1) 3d sentence	456.481, 456.482.
450.23(a)(1) 4th sentence	Redundant.
450.23(a)(1)(i)	456.170, 456.270.
450.23(a)(1)(ii)	456.180, 456.280.
450.23(a)(1)(iii)	456.281.
450.23(a)(1)(iv)	456.170, 456.181, 456.270.
450.23(a)(2)(i) and (ii)	456.602.
450.23(a)(2)(iii)	456.603.
450.23(a)(3)(ii)	456.604.
450.23(a)(3)(i)	456.605.
450.23(a)(3)(iii)	456.606, 456.607.
450.23(a)(3)(iv)	Redundant.
450.23(a)(3)(v) 1st and 2d sentences.	456.608.
450.23(a)(3)(v) 3d sentence	456.609.

PART 450—Continued

Old section	New section
450.23(a)(3)(v)(A)-(F)	456.610.
450.23(a)(4)(i)	456.611.
450.23(a)(4)(ii)	456.612.
450.23(a)(4)(iii)	456.613.
450.23(b)	456.614.
450.23(c)	Unnecessary.
450.24(a) Introductory paragraph except parenthetical note.	456.2.
450.24(a) Parenthetical note	456.601.
450.24(a)(1) Introductory paragraph.	456.370.
450.24(a)(1)(i)(A)-(C) 1st sentence.	456.370.
450.24(a)(1)(i)(C) 2d sentence	456.371.
450.24(a)(1)(ii)	456.380.
450.24(a)(1)(iii)	456.381.
450.24(a)(2)(i)	456.602.
450.24(a)(2)(ii)	456.603.
450.24(a)(3)(i)	456.605.
450.24(a)(3)(ii)	456.604.
450.24(a)(3)(iii)	456.606.
450.24(a)(3)(iv)	456.607.
450.24(a)(3)(v) 1st to 3d sentences.	456.608.
450.24(a)(3)(v) 4th sentence	456.609.
450.24(a)(3)(v)(A)-(G)	456.610.
450.24(a)(4)(i)	456.611.
450.24(a)(4)(ii)	456.612.
450.24(a)(4)(iii)	456.613.
450.24(b)	Unnecessary.
450.24(c)	456.614.
450.30(a)(1)	447.201.
450.30(a)(2)(i), (ii)	447.261.
450.30(a)(2)(iii)	Redundant.
450.30(a)(3) introductory paragraph, words before "as determined".	447.273.
450.30(a)(3) introductory paragraph, words after "cost-related basis".	447.221.
450.30(a)(3)(i)(A)	447.275.
450.30(a)(3)(i)(B)	447.274.
450.30(a)(3)(i)(C)	447.276.
450.30(a)(3)(i)(D)	447.274.
450.30(a)(3)(i)(E)	447.277.
450.30(a)(3)(i)(F)	447.277.
450.30(a)(3)(ii) introductory paragraph, 1st sentence, words before "and shall describe".	Surplusage.
450.30(a)(3)(ii) introductory paragraph, 1st sentence words after "of this section".	447.290.
450.30(a)(3)(ii) introductory paragraph, 2d sentence.	447.294.
450.30(a)(3)(ii)(A)	447.294.
450.30(a)(3)(ii)(B)	447.291.
450.30(a)(3)(ii)(C)	Surplusage.
450.30(a)(3)(ii)(D)	447.292.
450.30(a)(3)(ii)(E) words before "which audits shall".	447.293.
450.30(a)(3)(ii)(E) words after "exceptional profiles".	Surplusage.
450.30(a)(3)(ii)(F)	447.295.
450.30(a)(3)(ii)(G)	447.296.
450.30(a)(3)(iii) introductory paragraph.	447.278.
450.30(a)(3)(iii)(A)	447.279.
450.30(a)(3)(iii)(B)	447.281.
450.30(a)(3)(iii)(C)	447.282, 447.283.
450.30(a)(3)(iii)(D)	447.284.

PART 450—Continued

Old section	New section
450.30(a)(3)(iv) introductory paragraph.	447.301.
450.30(a)(3)(iv)(A)	447.302.
450.30(a)(3)(iv)(B)	447.303.
450.30(a)(3)(iv)(C)	447.304.
450.30(a)(3)(iv)(D)	447.305.
450.30(a)(3)(iv)(E)	447.306.
450.30(a)(3)(iv)(F)	447.307.
450.30(a)(3)(v)	447.311.
450.30(a)(3)(vi)	447.272.
450.30(a)(4)	447.252.
450.30(a)(5)	447.202.
450.30(a)(6)	447.203.
450.30(a)(7)	447.204.
450.30(a)(8)	447.15.
450.30(a)(9)	Obsolete.
450.30(b) introductory paragraph, 1st sentence.	447.252.
450.30(b) introductory paragraph, 2d sentence.	Surplusage.
450.30(b) introductory paragraph, 3d sentence.	447.252.
450.30(b) introductory paragraph, last sentence.	447.40.
450.30(b)(1) words before "or, in the case of".	447.262.
450.30(b)(1) words after "for such services".	Redundant.
450.30(b)(2) introductory paragraph.	447.331.
450.30(b)(2)(i)	447.333.
450.30(b)(2)(ii)	447.332.
450.30(b)(2)(iii)	447.332.
450.30(b)(2)(iv) 1st sentence	447.334.
450.30(b)(2)(iv) 2d sentence	Redundant.
450.30(b)(3)(i), (ii)(A)	447.341.
450.30(b)(3)(ii)(B)	Obsolete.
450.30(b)(3)(ii)(C)	447.341.
450.30(b)(4)	447.351.
450.30(b)(5)	447.321, 447.322.
450.30(b)(6)(i)	447.316.
450.30(b)(6)(ii)	447.315.
450.30(b)(6)(iii)	447.315.
450.30(b)(7)	447.361.
450.30(c)	447.252.
450.30(d)(1)	447.252.
450.30(d)(2)	447.40.
450.31	433.135.
450.41	431.105.
450.70	431.115.
450.71	433.37.
450.80(a)(1)	455.11, 455.12, 455.13.
450.80(a)(2)	455.13.
450.80(a)(3)	455.13.
450.80(a)(4)	455.17.
450.80(a)(5)(i)	455.18.
450.80(a)(5)(ii)	455.19.
450.80(a)(5)(iii)	455.18.
450.80(a)(6)	455.20.
450.80(a)(7)	455.22.
450.80(a)(8)	455.21.
450.80(b)(1)	455.14.
450.80(b)(2)	455.15, 455.16.
450.80(c)	455.23.
450.80(d)	455.21.
450.90(a)	433.111.
450.90(b)(1)	433.112.
450.90(b)(2)	433.113.
450.90(b)(3)	433.114.
450.90(b)(4)	Unnecessary.

PART 450—Continued

Old section	New section
450.100 except (c), words "excluding * * * Massachusetts".	431.610.
450.100(c), words "excluding * * * Massachusetts".	442.12.
450.210	447.35.
450.220	447.30.

PART 451

Old section	New section
451.10	431.615.

PART 452

Old section	New section
452.10(a)	431.700.
452.10(b)(1)	431.701, 431.704.
452.10(b)(2)	431.701.
452.10(b)(3)	431.706.
452.10(b)(4)	431.701.
452.10(b)(5)	431.701.
452.10(b)(6)	431.710.
452.10(b)(7)	431.714.
452.10(c)	431.702.
452.10(c)(1)	431.703.
452.10(c)(2)	431.705.
452.10(c)(2)(i)	431.707.
452.10(c)(2)(ii)	431.708.
452.10(c)(2)(iii) 1st sentence	431.709.
452.10(c)(2)(iii) 2d and 3d sentences.	431.710.
452.10(c)(2)(iv)	431.711.
452.10(c)(2)(v)	431.712.
452.10(c)(2)(vi)	431.713.
452.10(d)	431.714.
452.10(e)	431.715.

NOTE: This list includes only new sections based on regulations existing before recodification. Sections containing new material that is introductory or explanatory have not been included.

PART 431

New section	Old section
431.12	446.10.
431.51	449.20.
431.52	448.40(a).
431.53	449.10(a)(5)(ii).
431.105	450.41.
431.107	450.21.
431.110	449.10(a)(11).
431.115	450.70.
431.501	449.82(a).
431.502	449.82(b)(1)-(7), (9)-(11).
431.503	449.82(c)(1)(i)-(ix).
431.504	449.82(c)(1)(x).
431.510	449.82(c)(3).
431.511	449.82(c)(4).

PART 431—Continued

New section	Old section
431.512	449.82(c)(2)
431.521	449.82(b)(8)
431.522	449.82(c)(5)(xvi)
431.523–431.526	449.82(c)(5) introductory paragraph words before "a State plan for"
431.527	449.82(c)(5) introductory paragraph words after "and (2) of this section" and (i), (iv)
431.528	449.82(c)(5)(ii)
431.529	449.82(c)(5)(v) words before "which shall be"
431.530	449.82(c)(5)(vi)
431.531	449.82(c)(5)(vii)
431.532	449.82(c)(5)(viii), (ix)
431.533	449.82(c)(5)(x)
431.534	449.82(c)(5)(xi)
431.535	449.82(c)(5)(xii)
431.536	449.82(c)(5)(xiii)
431.537	449.82(c)(5)(xiv)
431.540	449.82(c)(6)(i)
431.541	449.82(c)(5)(v) words after "period of enrollment" and (6)(ii)
431.542	449.82(c)(6)(iii)
431.543	449.82(c)(6)(iv)
431.544	449.82(c)(6)(v)
431.545	449.82(c)(6)(vi)
431.546	449.82(c)(6)(vii)
431.547	449.82(c)(6)(viii)
431.548	449.82(c)(6)(ix)
431.549	449.82(c)(6)(x)
431.550	449.82(c)(6)(xi)
431.557–431.560	449.82(c)(5) words before "a State plan for"
431.565	449.82(c)(5)(xv)
431.568	449.82(c)(5) introductory paragraph words after "and (2) of this section" and (i) 1st sentence, (iv)
431.569	449.82(c)(5)(ii)
431.570	449.82(c)(5)(v) words before "which shall be"
431.571	449.82(c)(5)(vi)
431.572	449.82(c)(5)(vii)
431.573	449.82(c)(5)(viii) and (ix)
431.574	449.82(c)(5)(x)
431.575	449.82(c)(5)(xi)
431.576	449.82(c)(5)(xii)
431.577	449.82(c)(5)(xiii)
431.578	449.82(c)(5)(xiv)
431.580	449.82(c)(6)(i)
431.581	449.82(c)(5)(v) words after "period of enrollment" and (6)(ii)
431.582	449.82(c)(6)(iii)
431.583	449.82(c)(6)(iv)
431.584	449.82(c)(6)(v)
431.585	449.82(c)(6)(vi)
431.586	449.82(c)(6)(vii)
431.587	449.82(c)(6)(ix)
431.588	449.82(c)(6)(x)
431.589	449.82(c)(6)(xi)
431.591	449.82(d)(1)
431.592	449.82(d)(2)
431.593	449.82(d)(3)
431.594	449.82(d)(4)(iii)
431.595	449.82(d)(4)(iv)
431.596	449.82(d)(4)(v)
431.597	449.82(d)(4)(i), (ii)
431.610	450.100
431.615	451.10
431.625	449.41
431.700	452.10(a)
431.701	452.10(b)(1), (2), (4), (5)
431.702	452.10(c)
431.703	452.10(c)(1)
431.704	452.10(b)(1)
431.705	452.10(c)(2)
431.706	452.10(b)(3)
431.707	452.10(c)(2)(i)
431.708	452.10(c)(2)(ii)
431.709	452.10(c)(2)(iii) 1st sentence
431.710	452.10(b)(6) and 452.10(c)(2)(iii) 2d and 3d sentences
431.711	452.10(c)(2)(iv)
431.712	452.10(c)(2)(v)
431.713	452.10(c)(2)(vi)
431.714	452.10(b)(7) and 452.10(d)
431.715	452.10(e)

PART 432

New section	Old section
432.2	446.151
432.10	446.160
432.30	446.170
432.31	446.165
432.32	446.166
432.50	446.175
432.55	446.180
432.60	446.185

PART 433

New section	Old section
433.36	449.70
433.37	450.71
433.111	450.90(a)
433.112	450.90(b)(1)
433.113	450.90(b)(2)
433.114	450.90(b)(3)
433.135	450.31

PART 435

New section	Old section
435.2	"Note" at beginning of 448.1

PART 435—Continued

New section	Old section
435.10	448.1(b) 1st sentence. 448.1(c) 1st sentence. 448.1(e). 448.3(a)(1)(ii)(c), 1st sentence.
435.110	448.1(b)(1)(i). 448.10(b)(1)(i).
435.111	448.1(b)(1)(ii).
435.112	448.1(b)(1)(iii).
435.113	448.1(b)(3)(i).
435.114	448.1(b)(3)(ii).
435.120	448.1(b)(2)(i).
435.121	448.1(b)(2)(iii).
435.122	448.1(b)(3)(i).
435.130	448.1(b)(2)(iv).
435.131	448.1(b)(2)(v).
435.132	448.1(b)(2)(vi).
435.133	448.1(b)(2)(vii).
435.134	448.1(b)(3)(ii).
435.135	448.1(b)(2)(viii).
435.200	448.1(c) 1st sentence.
435.210	448.1(c)(1).
435.211	448.1(c)(2).
435.220	448.1(c)(6).
435.221	448.1(c)(5).
435.222	448.1(c)(4).
435.223(a)	448.1(c)(3).
435.230	448.1(b)(2)(ii) 448.2(d).
435.231	448.2(e).
435.301	448.1(a)(2)(i). 448.1(d)(1).
435.310	448.1(d)(1).
435.320	448.1(d)(1).
435.321	448.1(a)(1)(ii)(A) and (d)(1).
435.325	445.1(d)(2).
435.401	448.2(a) and (c).
435.402	448.50.
435.403	448.40(b).
435.404	448.3(b)(6).
435.510	448.1(c) and 448.2(b)(1).
435.520	448.30(a), (b)(2), (3).
435.530	448.70(a)(1).
435.531	448.70(a)(2), (3), (b), (c)(1).
435.540	448.80(a)(1).
435.541	448.80(a)(2), (b), (c)(1).
435.602	448.3(b)(1)(iii).
435.603	448.3(b)(1)(ii).
435.711	448.3(a)(1)(i).
435.712	448.3(b)(1)(i), (5)(i)–(iii).
435.721	448.2(e), 448.3(a)(1)(ii)(A) and (B), (b)(2)(iii).
435.722	448.2(e).
435.723	448.3(b)(1)(i), (2).
435.724	448.3(b)(1)(i), (3).
435.725	448.3(b)(7), (8).
435.731	448.3(b)(7), (b)(9).
435.732	448.1(a)(1)(ii), (b)(2)(iii), 448.3(b)(8), (9).
435.733	448.3(b)(8).
435.734	448.3(b)(4).
435.740	448.1(a)(3).
435.811	448.3(b)(2)(iv), (3)(v), (5)(v), (c)(1)(i). 448.4(b)(4)(ii).
435.812	448.3(c)(1)(ii)(B), (iii).
435.813	448.3(b)(7).
435.814	448.3(b)(2)(iv), (3)(v), (5)(iv), (c)(1)(ii)(B), (iii).
435.815	448.3(b)(2)(iv), (7).
435.816	448.3(b)(3)(v), (5)(iv)(c)(1)(ii)(A), 448.4(b)(4)(ii)(B).
435.821	448.3(b)(5).
435.822	448.3(b)(2), (3).
435.823	448.3(b)(4).
435.831	448.1(a)(2)(ii), (b)(2)(iv), (3)(v), (5)(iv), (c)(2), (3), (4).
435.832	448.3(b)(7), (8).
435.840	448.3(c)(1)(iv).
435.841	448.3(c)(1)(iv).
435.845	448.3(c)(3), (4).
435.1001	448.4(a), 448.70(c)(2), and 448.80(c)(2).
435.1002	448.4(b)(1), (5), (8).
435.1003	448.4(b)(7).
435.1004	448.4(b)(6).
435.1005	448.4(b)(3), (c).
435.1006	448.3(a)(1)(ii)(B)(2) 448.4(b)(3), (c).
435.1007	448.4(b)(4), (c).
435.1008	448.4(b)(2), 448.60(a)(1)-(3)(i), (iv).
435.1009	448.60(a)(3)(ii), (iii)(b)(1)-(11), 449.10(d)(1).
435.1010	448.4(d).
435.1011	448.4(e).

PART 436

New section	Old section
436.10	448.10(b), 448.21(a).
436.110	448.10(b)(1)(i).
436.111	448.10(b)(1)(iii).
436.112	448.10(b)(3).
436.115	448.10(b)(1)(ii).
436.116(a)	448.10(b)(4).
436.210	448.10(b)(2)(i).
436.211	448.10(b)(2)(ii).
436.212	448.10(b)(2)(iii).
436.220	448.10(b)(2)(vi).
436.221	448.10(b)(2)(v).
436.222	448.10(b)(2)(iv).
436.230	448.11.
436.301	448.10(b)(5) 1st sentence.
436.310	448.10(b)(5) 1st sentence.
436.320	448.10(b)(5) 1st sentence.
436.330	448.10(b)(5) 1st sentence.
436.401	448.10(c)(1), (3)(4).
436.402	448.50.
436.403	448.40.
436.404	448.21(a)(2)(vi).
436.510	448.10(c)(3).
436.520	448.30.
436.530	448.70.
436.531	448.70.
436.540	448.80.
436.541	448.80.
436.602	448.21(a)(2)(ii).

Redesignation Table III

PART 436—Continued

New section	Old section
436.603	448.21(a)(2)(i)(C) 1st sentence words after "applicant or recipient" and 2d sentence
436.711	448.21(a)(1)(i), (a)(2)(iv), (v).
436.811	448.21(a)(3)(i)(A).
436.812	448.21(a)(3)(i)(B); 448.21(a)(2)(v).
436.813	448.21(a)(3)(1)(C).
436.821	448.21(a)(2)(iv), (v).
436.831	448.21(a)(3)(ii), (iii), (iv).
436.832	448.21(a)(3)(i)(C) except 1st and 2d sentence.
436.840	448.21(a)(3)(i)(D).
436.845	448.21(a)(3)(iii), (iv).
436.1001	448.10(d).
436.1002(a)	448.10(d)(1).
436.1002(b)	448.10(d)(3).
436.1003	448.10(d)(4).
436.1004(a)	448.10(d)(2) paragraph after (vi).
436.1004(b)	448.60(a)(3)(i).
436.1004(c)	448.60(a)(3)(iv).
436.1005	448.60.

PART 440

New section	Old section
440.2	449.10(b) introductory paragraph 449.10(d)(1).
440.10	449.10(b)(1).
440.20	449.10(b)(2).
440.30	449.10(b)(3).
440.40	449.10(b)(4)(i)(A), (C), (ii) 1st sentence.
440.50	449.10(b)(5).
440.60	449.10(b)(6).
440.70	449.10(b)(7).
440.80	449.10(b)(8).
440.90	449.10(b)(9).
440.100	449.10(b)(10).
440.110	449.10(b)(11).
440.120	449.10(b)(12).
440.130	449.10(b)(13).
440.140	449.10(b)(14).
440.150	449.10(b)(15)(i)(A) 1st sentence, (B), (iii).
440.160	449.10(b)(16) introductory paragraph.
440.170	449.10(b)(17).
440.210	449.10(a)(1).
440.220	449.10(a)(2).
440.230	449.10(a)(5)(i).
440.240	449.10(a)(6) introductory paragraph and (7).
440.250	449.10(a)(6)(i)-(vii).
440.260	449.10(a)(8).

PART 441

New section	Old section
441.11	449.10(d)(3).
441.13	449.10(c)(1), (2).
441.15	449.10(a)(4).
441.20	449.10(a)(9).
441.30	449.10(a)(10).
441.40	449.10(c)(4).
441.51	449.10(a)(3) introductory paragraph.
441.52	449.10(b)(4)(ii) 2d and 3d sentences.
441.53	449.10(a)(3)(iv).
441.54	449.10(a)(3)(i).
441.55	449.10(a)(3)(ii).
441.56	449.10(a)(3)(iii).
441.151	449.10(b)(16)(i), (ii).
441.152	449.10(b)(16)(iii) introductory paragraph.
441.153	449.10(b)(16)(iii)(A) words after "of these regulations" and (C)-(E).
441.154	449.10(b)(16)(iii)(A) words before "and for whom".
441.155	449.10(b)(16)(iv)(B).
441.156	449.10(b)(16)(iv)(C).
441.181	449.10(c)(5)(ii)(A)-(G).
441.182	449.10(c)(5)(i) and (ii) introductory paragraph.
441.201	449.101.
441.202	449.102.
441.203	449.103.
441.204	449.104.
441.205	449.105.
441.206	449.106.
441.207	449.107.
441.208	449.108.

PART 442

New section	Old section
442.1	449.33(a)(1)(ii) words "pursuant to section 1910 of the Act" and (iii) words "pursuant to section 1905 of the Act".
442.10	449.33(a) introductory paragraph.
442.12	449.33(a)(1) except words "(including hospitals)," (6) 2d sentence, words after "of one year", 3d sentence, words before "except that" and after "period of certification"; 450.100(c).
442.15	449.33(a)(6) 2d sentence, words before "and the effective date", 3d sentence, words before "or may elect".
442.16	449.33(a)(6) 4th sentence.
442.20	449.33(a)(9).
442.30	449.10(b)(4)(i)(C).

PART 442—Continued

New section	Old section
442.100	449.33(a)(4)(i) and (ii) introductory paragraph.
442.101	449.33(a)(1) introductory paragraph except words "(including hospitals)," (i), (ii) words before "and in the case" except words "pursuant to section 1910 of the Act", (iii) words before "and in the case" except words "Pursuant to section 1905 of the Act", (2) introductory, paragraph except words "(including hospitals and skilled nursing facilities)", (4)(i), (ii) introductory paragraph, (v)
442.105	449.33(a)(4)(ii), (iv)(A), (B)(*1*)
442.110	449.33(a)(4)(iii) last sentence.
442.111	449.33(a)(4)(iii) last sentence.
442.112	449.33(a)(2)(i) except words "in accordance with paragraph (a)(4)(iii) of this section".
442.113	449.33(a)(2)(ii) except words "in accordance with paragraph (a)(4)(iii)(A) of this section", and paragraphs (A)(*2*) and (*3*) and (D)
442.115	449.33(a)(2)(ii) (A)(*3*)
442.200	449.33(a)(1)(iii) words before "except that", except words "pursuant to section 1905 of the Act".
442.201	449.10(a)(11), (b)(4)(i)(B)
442.202	449.33(a)(1)(i) words after "this chapter", (ii) words after "title XVIII of the Act," (iii) words before "except that" except words "pursuant to section 1905 of the Act".
442.250	449.33(a)(2) introductory paragraph except words "(including hospitals and skilled nursing facilities)"
442.251	449.10(a)(11)(b) (15)(i)(A)
442.252	449.10(b)(15)(i) (C)
442.253	449.33(a)(1)(i) words after "this chapter"
442.254	449.10(b)(15)(ii)
442.300	449.12(a) introductory paragraph
442.301	449.12(a)(1)
442.302	449.12(a)(1)(i) 1st sentence
442.303	449.12(b)(1)
442.304	449.12(b)(2).
442.305	449.12(a)(1)(ii) (A).
442.306	449.12(a)(1)(ii) (A)(*1*)(*i*).
442.307	449.12(a)(1)(ii) (A)(*1*)(*ii*), (*iii*).
442.308	449.12(a)(1)(ii) (A)(*2*).
442.309	449.12(a)(1)(ii) (A)(*3*).
442.310	449.12(a)(ii)(A) (*4*).
442.311	449.12(a)(1)(ii) (B).
442.312	449.12(a)(1)(ii) (C).
442.313	449.12(a)(1)(iv), (v).
442.314	449.12(a)(1)(vi).
442.315	449.12(a)(1)(vii).
442.316	449.12(a)(2).
442.317	449.12(a)(3).
442.318	449.12(a)(4)(i)(A)–(E), (ii), (iii).
442.319	449.12(a)(4)(i)(C).
442.320	449.12(a)(1)(iii).
442.321	449.12(a)(5) introductory paragraph, (iii)
442.322	449.12(a)(5)(i)
442.323	449.12(a)(5)(ii), undesignated paragraph following paragraph (iii).
442.324	449.12(a)(6)(i) 1st sentence, (iv)
442.325	449.12(a)(6)(i) 2d and 3d sentences and paragraph (a)
442.326	449.12(a)(6)(i) 2d sentence, (iii)
442.327	449.12(a)(6)(ii).
442.328	449.12(a)(6)(v), (vi)
442.329	449.12(a)(6)(vii), (viii)
442.330	449.12(a)(6)(ix).
442.331	449.12(a)(7)(i), (vi), (vii)
442.332	449.12(a)(7)(ii)–(iv)
442.333	449.12(a)(8)(i)
442.334	449.12(a)(8)(ii).
442.335	449.12(a)(8)(iii)
442.336	449.12(a)(8)(v).
442.337	449.12(a)(8)(iv), (vi)
442.338	449.12(a)(9) introductory paragraph
442.339	449.12(a)(9)(i) introductory paragraph and (A)–(C)
442.340	449.12(a)(9)(ii).
442.341	449.12(a)(9)(iv).
442.342	449.12(a)(9)(v).
442.343	449.12(b)(3).
442.344	449.12(b)(4)
442.345	449.12(b)(5)
442.346	449.12(b)(6)
442.400	449.13 introductory paragraph, 1st sentence, words after "July 18, 1977"
442.401	449.12(c)(3) introductory paragraph, 2d sentence, and paragraphs (i)–(ix), 449.13(c)(3)(i), (h)(1), (5)–(9)
442.402	449.13(a)(1)(i)
442.403	449.13(a)(1)(ii).
442.404	449.12(a)(1)(ii)(B).
442.405	449.12(a)(1)(ii)(C)

PART 442—Continued

New section	Old section
442.406	449.12(a)(1)(iii), 449.13(a)(1)(iii)
442.407	449.13(a)(1)(iv)
442.408	449.13(a)(1)(v)
442.409	449.13(a)(1)(vi), (vii)(h)(2) (4)
442.410	449.13(c)(2), 449.13(a)(1)(viii), (h)(2)
442.411	449.12(c)(3) introductory paragraph, 1st sentence, 449.13(c)(3)(vi)
442.412	449.13(a)(1)(ix)
442.413	449.13(a)(1)(x)
442.414	449.13(a)(1)(xi)
442.415	449.12(a)(1)(vii)
442.416	449.13(e)
442.417	449.12(a)(3)(i)
442.418	449.12(c)(1), 449.13(a)(2)(i) introductory paragraph 1st sentence (iii), (iv)
442.419	449.13(a)(2)(ii)
442.420	449.13(a)(2)(i) introductory paragraph 2d sentence, and (A) (B)
	442.421
	449.13(a)(2)(v)
442.422	449.13(a)(2)(vi)
442.423	449.13(a)(2)(vii)
442.424	449.13(a)(2)(viii), (ix), (d)(2)(iv)
442.425	449.12(a)(2), 449.13(a)(viii), (x)
442.426	449.13(a)(2)(xi), (xii)
442.427	449.13(a)(3)(ii), (vi), (xi)
442.428	449.13(a)(3)(iii), (iv)
442.429	449.13(a)(3)(v)
442.430	449.13(a)(3)(vii)
442.431	449.13(a)(3)(viii)
442.432	449.13(a)(3)(ix), (x)
442.433	449.13(b)(1)(i), (ii)
442.434	449.13(b)(1)(iii)
442.435	449.13(b)(1)(iv)-(vi)
442.436	449.13(b)(1)(vii)
442.437	449.13(b)(1)(viii)-(x)
442.438	449.13(b)(1)(xi) introductory paragraph (A)-(C), (D) 2d sentence
442.439	449.13(b)(1)(xi)(D) 1st sentence, (E)
442.440	449.13(b)(1)(xii)
442.441	449.13(b)(1)(xiii), (h)(10)
442.442	449.13(b)(2)
442.443	449.13(b)(3)
442.444	449.13(b)(4)
442.445	449.13(b)(5)
442.446	449.12(a)(6)(i)
442.447	449.12(a)(6)(i), 449.13(b)(6)(i)
442.448	449.12(a)(6)(i), 449.13(b)(6)(ii)
442.449	449.13(b)(6)(iii), (iv), (xiii)
442.450	449.13(b)(6)(v), (vi), (xi)
442.451	449.13(b)(6)(vii), (viii), (x)
442.452	449.13(b)(6)(ix)
442.453	449.13(b)(6)(xii)
442.454	449.13(c)(1)

PART 442—Continued

New section	Old section
442.455	449.13(c)(1)(i)
442.456	449.13(c)(1)(ii)
442.457	449.13(c)(2)(i)
442.458	449.13(c)(2)(ii)
442.459	449.13(c)(2)(iii)
442.460	449.13(c)(2)(iv)
442.461	449.13(c)(2)(v)
442.462	449.13(c)(2)(vi)
442.463	449.13(c)(3)(i)-(v)
442.464	449.13(c)(3)(vi)
442.465	449.13(c)(4)(i)
442.466	449.13(c)(4)(ii), (iii), (iv) introductory paragraph, 1st sentence
442.467	449.13(c)(4)(iv) introductory paragraph, 2d sentence, (A)-(C), (vi), (vii) 3d sentence
442.468	449.13(c)(4)(v)
442.469	449.13(c)(4)(vii) 1st and 2d sentences
442.470	449.13(c)(4)(vii) 4th and 5th sentences
442.471	449.13(c)(4)(viii), (ix)
442.472	449.13(c)(4)(x), (xi)
442.473	449.13(c)(4)(xii)-(xiv)
442.474	449.12(a)(9) introductory paragraph, 449.13(c)(5)(i), (ii), (viii)
442.475	449.13(c)(5)(iii), (iv)
442.476	449.12(a)(3)(ii), 449.13(c)(5)(vi), (vii)
442.477	449.13(c)(5)(v)
442.478	449.12(a)(9)(v) words before "and, in the case of," 449.13(c)(6)(i), (ii)
442.479	449.13(c)(6)(iii)
442.480	449.13(c)(6)(iv), (v)
442.481	449.12(a)(9)(i)-(iv)
442.482	449.13(c)(7)(i) 2d sentence, (ii), (iii)
442.483	449.13(c)(7)(i) 1st sentence, (iv), (vi)
442.484	449.13(c)(7)(vii), (ix)-(xi)
442.485	449.13(c)(7)(viii)
442.486	449.13(c)(8)(i)-(iii)
442.487	449.13(c)(8)(iv)
442.488	449.13(c)(8)(v), (vi)
442.489	449.13(c)(9)(i), (v)
442.490	449.13(c)(9)(ii), (iv), (vi)
442.491	449.13(c)(10)(i), (v), (vi)
442.492	449.13(c)(10)(ii)
442.493	449.13(c)(10)(iii), (iv)
442.494	449.13(c)(11)(i)
442.495	449.13(c)(11)(ii)-(vi)
442.496	449.13(c)(12)(i), (ii)
442.497	449.13(c)(12)(iii), (iv)
442.498	449.13(c)(12)(v), (vi)
442.499	449.13(d)(1)(i)-(iii)
442.500	449.13(d)(2)(i)
442.501	449.13(d)(2)(ii)-(iv)
442.502	449.13(d)(3)
442.503	449.13(d)(4)
442.504	449.13(d)(5)
442.505	449.13(e)(1)(i)
442.506	449.13(e)(1)(ii), (iii)
442.507	449.12(a)(5) introductory paragraph, (i)
442.508	449.12(a)(5)(ii)

PART 442—Continued

New section	Old section
442.509	449.12(a)(5)(ii), undesignated paragraph following paragraph (iii)
442.510	449.13(f)(1)(v).
442.511	449.12(a)(6)(ix), 449.13(f)(1)(iv)
442.512	449.13(f)(2).
442.513	449.13(g)(1)
442.514	449.13(g)(2)
442.515	449.13(g)(3).
442.516	449.13(g)(4)

PART 447

New section	Old section
447.10	449.31
447.15	450.30(a)(8)
447.25	449.32
447.30	450.220
447.35	450.210
447.40	450.30(b) introductory paragraph, last sentence, and (d)(1)
447.51	449.40(a)(1) words before "and no deduction" and (2) introductory paragraph
447.52	449.40(a)(2)(i), (ii)
447.53	449.40(a)(1) words after "under the plan" and (3) introductory paragraph
447.54	449.40(a)(3) (i), (ii), (iv)
447.55	449.40(a)(3)(iii)
447.56	449.40(a)(3)(v)
447.57	449.40(a)(3)(vi) 1st sentence
447.58	449.40(a)(3)(vi) 2d sentence
447.59	449.40(b)
447.201	450.30(a)(1)
447.202	450.30(a)(5)
447.203	450.30(a)(6)
447.204	450.30(a)(7)
447.251	450.30(a)(3) introductory paragraph, words after "cost-related basis."
447.252	450.30(b) introductory paragraph, except 2d and last sentences (C), (d)(1)
447.261	450.30(a)(2) except (iii)
447.262	450.30(b)(1) except words after "for such services"
447.272	450.30(a)(3)(vi)
447.273	450.30(a)(3) introductory paragraph, words before "as determined"
447.274	450.30(a)(3)(i)(B), (D)
447.275	450.30(a)(3)(i)(A)
447.276	450.30(a)(3)(i)(C)
447.277	450.30(a)(3)(i)(E), (F)
447.279	450.30(a)(3)(iii)(A)
447.281	450.30(a)(3)(iii)(B)

PART 447—Continued

New section	Old section
447.282	450.30(a)(3)(iii)(C).
447.283	450.30(a)(3)(iii)(C)
447.284	450.30(a)(3)(iii)(D)
447.290	450.30(a)(3)(ii) introductory paragrap works after "of this section".
447.291	450.30(a)(3)(ii)(B)
447.292	450.30(a)(3)(ii)(D)
447.293	450.30(a)(3)(ii)(E) excep words after "exceptional profiles
447.294	450.30(a)(3)(ii) introductory paragrap 2d sentence and (A)
447.295	450.30(a)(3)(ii)(F)
447.296	450.30(a)(3)(ii)(G)
447.302	450.30(a)(3)(iv)(A)
447.303	450.30(a)(3)(iv)(B)
447.304	450.30(a)(3)(iv)(C)
447.305	450.30(a)(3)(iv)(D)
447.306	450.30(a)(3)(iv)(E)
447.307	450.30(a)(3)(iv)(F)
447.311	450.30(a)(3)(v)
447.315	450.30(b)(6) (ii), (iii)
447.316	450.30(b)(6)(i)
447.321	450.30(b)(5)
447.322	450.30(b)(5)
447.341	450.30(b)(3) except (ii)(B)
447.351	450.30(b)(4)

PART 455

New section	Old section
455.11	450.80(a)(1) last sentence
455.12	450.80(a)(1) 1st sentence
455.13	450.80(a)(1) 1st sentence, (2), (3)
455.14	450.80(b)(1)
455.15, 455.16	450.80(b)(2)
455.17	450.80(a)(4)
455.18	450.80(a)(5)(i), (iii)
455.19	450.80(a)(5)(ii), (8)
455.20	450.80(a)(6)
455.21	450.80(d)
455.22	450.80(a)(7)
455.23	450.80(c)
455.104	449.33(a)(3)
455.300	450.310

PART 456—UTILIZATION CONTROL

New section	Old section
456.2	450.18 introductory paragraph, 450.23(a 450.24(a) introductor paragraph except parenthetical note
456.3	450.18(a), (iii), (4), (5
456.4	450.18(b)
456.5	450.18(c).

Redesignation Table III

PART 456—UTILIZATION CONTROL—Continued

New section	Old section
456.6	450.18(d) words before "and will perform."
456.22	450.18(a)(1)(i)
456.23	450.18(a)(1)(ii)
456.60	450.18(a)(2)
456.80	450.18(a)(3)(i) and (ii)
456.101	450.19(a) first two words and words after "intermediate care facility."
456.102	450.19(a)(1) introductory paragraph
456.105	450.19(a)(1)(ii) introductory paragraph and (v)
456.106(b) and (c)	450.19(a)(1)(ii)
456.111	450.19(a)(1)(vii) and (ix) words after "admission is necessary" and before "based on the patient's."
456.112	450.19(a)(1)(vi)
456.113	450.19(a)(1)(i)
456.121	450.19(a)(1)(viii) introductory paragraph words before "within one working day."
456.122	450.19(a)(1)(viii)(B), 1st and 2d sentences except words after "criteria and" and before "are applied."
456.123	450.19(a)(1)(viii) introductory paragraph words after "of such application", (B) 1st and 2d sentences, (C), (D), (E) words before "and written notification", (F) words before "written notification thereof" and (ix) words before "is recorded."
456.124	450.19(a)(1)(viii)(E) words after "shall be considered final" and (F) words after "is not necessary."
456.125	450.19(a)(1)(viii) introductory paragraph words before "by the committee" except parenthetical notes.
456.126	450.19(a)(1)(viii)(A)
456.127	450.19(a)(1)(viii) parenthetical note
456.128	450.19(a)(1)(ix)
456.129	450.19(a)(1)(iii) (A) and (C), and (iv)
456.132	450.19(a)(1)(x)(C), 1st and 2d sentences except words after "criteria and" and before "are applied."
456.133	450.19(a)(1)(x)(D) words after "shall be determined."
456.134	450.19(a)(1) (iii)(C) and (iv)
456.135	450.19(a)(1)(x) (B), (C) words before "The single State agency", (D), (E), (F), (G) words before "and written notification", and (H) words before "written notification."
456.136	450.19(a)(1)(x)(G) words after "shall be considered final" and (H) words after "has not been justified."
456.137	450.19(a)(1)(xi)(A)
456.141	450.19(a)(1)(x)
456.142	450.19(a)(1)(xii)(B), (xiii)(B) and (xiv)
456.143	450.19(a)(1)(xii)(A) 3d and 4th sentences
456.144	450.19(a)(1)(xii)(A) 1st sentence
456.145	450.19(a)(1)(xii)(A) 5th sentence
456.160	450.19(a)(3)
456.170	450.21(a)(1) introductory paragraph 1st and 2d sentences, (i) and (ii)
456.171	450.18(a)(1)(iv) last sentence
456.180	450.18(a)(3)(ii), 450.23(a)(1) introductory paragraph 1st and 2d sentences, (ii), and (iv)
456.201(a)	450.19(a) introductory paragraph 1st words "mental hospital", words after "review plan", and (2) introductory paragraph
456.205	450.19(a)(2)(ii) introductory paragraph and (vi)
456.206(b) and (c)	450.19(a)(2)(iii)
456.211	450.19(a)(2)(viii), 1st, 2d sentence and (ix)(b) 1st sentence words after "is appropriate and."
456.212	450.19(a)(2)(vi)
456.213	450.19(a)(2)(x)
456.231	450.19(a)(2)(xiii) words before "or on before a specified date."
456.232	450.19(a)(2)(xiii) 1st sentence
456.233	450.19(a)(2)(xiv) words after "necessity of continued stay" and before "Subsequent reviews", and last sentence
456.234	450.19(a)(2)(xiv) words after "30 days after admission" and before "The assigned review dates", and (xv)(b) words after "date assigned."

PART 456—UTILIZATION CONTROL—Continued

New section	Old section
456.235	450.19(a)(2)(iii)(B) and (iv).
456.236	450.19(a)(2)(ix)(B), (C) 1st and 2d sentences, (D)–(G) words before "and written notification", and (H) words before "written notification."
456.237	450.19(a)(2)(ix)(G) words after "considered final" and (H) words after "mental hospital services."
456.238	450.19(a)(2)(ix)(A).
456.241	450.19(a)(2)(x)(A) 1st and 2d sentence.
456.242	450.19(a)(2)(iii)(A), (x)(B), and (xi).
456.243	450.19(a)(2)(x)(A) 3d and 4th sentences.
456.244	450.19(a)(2)(x)(A) last sentence words before "and (B)."
456.245	450.19(a)(2)(x)(A) 5th sentence.
456.260	450.18(a)(2).
456.270	450.23(a)(1) introductory paragraph 1st and 2d sentences, (i) and (iv).
456.271	450.18(a)(1)(v) last sentence.
456.280	450.18(a)(3)(ii), (iv), 450.23(a)(1) introductory paragraph 1st and 2d sentences and (ii).
456.281	450.18(a)(3)(iv), 450.23(a)(1)(iii).
456.301	450.19(a) introductory paragraph except "hospital, mental hospital" and "intermediate care facility."
456.302	450.19(a)(3) introductory paragraph.
456.305	450.19(a)(3)(ii) introductory paragraph and (v).
456.306(b) and (c)	450.19(a)(3)(iii)(A) and (B).
456.311	450.19(a)(3)(vii), (viii) introductory paragraph words after "such application" and before "and is either," and (ix)(C) words after "is appropriate" and before "At the expiration."
456.312	450.19(a)(3)(vi).
456.313	450.19(a)(3)(i).
456.321	450.19(a)(3)(viii) words before "on or before a specified date."
456.332	450.19(a)(3)(ix)(B) 2d sentence except words "and closer professional scrutiny."
456.333	450.19(a)(3)(viii)(A) words before "but at least."
456.334	450.19(a)(3)(viii)(A) words after "functional capabilities", (B), and (ix)(C) words after "date assigned."
456.335	450.19(a)(3)(iii)(B) and (iv).
456.336	450.19(a)(3)(ix)(A), (B) words before "The single State agency", (C), (D), (E), (F) words before "and written notification", and (G) words before "written notification."
456.337	450.19(a)(3)(ix)(F) words after "shall be considered final" and before "not later than" and words after "the assigned review date" and (G) words after "nursing facility services" and before "not later than" and words after "assigned review date."
456.338	450.19(a)(3)(ix)(F) words after "shall be sent except (1)–(4), and (G) words "shall be made except (1)–(4)."
456.341	450.19(a)(3)(x)(A) 1st and 2d sentences.
456.342	450.19(a)(3)(iii)(A), (x)(B
456.343	450.19(a)(3)(x)(A) 3d and 4th sentences.
456.344	450.19(a)(3)(x)(A) 6th sentence.
456.345	450.19(a)(3)(x)(A) 5th sentence.
456.346	450.18(a)(1)(iv).
456.347	450.18(a)(1)(iv).
456.348	450.18(a)(1)(iv).
456.360	450.18(a)(2).
456.370	450.24(a)(1)(i)(A)–(C) 1st sentence.
456.371	450.24(a)(1)(i)(C) 2d sentence.
456.372	450.18(a)(1)(v) last sentence.
456.380	450.18(a)(3)(ii), 450.24(a)(1)(ii).
456.381	450.24(a)(1)(iii).
456.401	450.19(a) introductory paragraph first word, words after "skilled nursing facility and" (4) 2d sentence except (i)–(vii).
456.402	450.19(a)(4) introductory paragraph parenthetical note.
456.405	450.19(a)(4)(ii)(A) 1st sentence except words "and by whom."

Redesignation Table III

PART 456—UTILIZATION CONTROL—Continued

New section	Old section
456.406	450.19(a)(4)(ii)(A) words after "How, when and"
456.407	450.19(a)(4)(ii)(B)
456.411	450.19(a)(4)(v) and (vii)(C) words after "determined and" and before "in accordance with"
456.412	450.19(a)(4)(iv)
456.413	450.19(a)(4)(i)
456.421	450.19(a)(4)(vi) words before "or more frequently" and words after "time of assessment"
456.4[illegible]	450.19(a)(4)(viii)(I) 1st sentence except words "and other professional [illegible]"
456.4[illegible]	450.19(a)(4)(v) 1st sentence, words after "for continued stay"
456.4[illegible]	450.19(a)(4)(v) 1st sentence, words after "for continued stay" and (vii)(C) words after "date assigned"
456.4[illegible]	450.19(a)(4)(i)
456.4[illegible]	450.19(a)(4)(vii)(A) words before "and written notification" and (D) words before "written notification"
456.43[illegible]	450.19(a)(4)(vii)(F) words after "shall be considered high" [illegible] words before "not less than" and words after "final determination" and (G) words after "intermediate care facility services" and before "not less than" and words after "final determination"
456.4[illegible]	450.19(a)(4)(vii)(F) words after "shall be considered [illegible]" [illegible] words after "intermediate care facility services" [illegible]
456.[illegible]	450.[illegible] 1st sentence
456.[illegible]	450.23(a)(1) 1st sentence
456.[illegible]	450.[illegible] 1st sentence

PART 456—UTILIZATION CONTROL—Continued

New section	Old section
456.505	[illegible] 1st sentence
456.506	450.19(b)(4)(ii) [illegible]
456.507	[illegible]
456.508	[illegible]
456.520	[illegible]
456.521	[illegible] 1st sentence [illegible]
456.522	[illegible]
456.523	[illegible] 1st sentence and (ii) 1st sentence
456.524	[illegible] 1st sentence and (ii) 1st sentence
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]
456.5[illegible]	[illegible]

Redesignation Table IV

This redesignation table has been developed as a reference tool only. The redesignations of specific sections and paragraphs from 45 CFR Parts 205, 206, and 208 apply only to the Medicaid program. The regulatory provisions under Parts 205, 206, and 208 that apply to the financial assistance programs (Title I, IV-A, X, XIV, and XVI of the Social Security Act) and the social services programs (title XX of the Act) remain in these parts; published at 44 FR 17927, Mar. 23, 1979.

CROSS REFERENCE: This table corrected at 45 FR 24882, Apr. 11, 1980, as seen in Redesignation Table VI of this title.

Old Section in 45 CFR	New Section in 42 CFR
205.10(a) to words before "where a State agency adopts"	431.205
205.10(a)(1)(ii) words after "right of appeal to a State agency hearing"	431.206
205.10(3)(1)(ii) words after "* * * 397 U.S. 254 (1970)	431.202
205.10(a) (2)-(3)	431.206
205.10(a)(4)(i)(A)	431.211
205.10(a)(4)(i)(B)	431.210
205.10(a)(4)(ii) words before "or of the AFDC * * *"	431.213
205.10(a)(4)(ii) words after "* * * death of a recipient * * *" to words before "(B) the agency * * *"	Deleted—unnecessary
205.10(a)(4)(ii) (B), (C), (E), (F), (H)	431.213
205.10(a)(4)(ii) (D), (G), (I)	Deleted—unnecessary
205.10(a)(4)(iii)	431.206, 431.210
205.10(a)(4)(iv)	431.214
205.10(a)(5) to words before "* * * unless the reason for * * *	431.220
205.10(a)(5) words after "* * * classes of recipients * * *" to words before "* * * (i) A request * * *"	Deleted—unnecessary
205.10(a)(5) (i), (ii), and (iii)	431.221
205.10(a)(5)(iv)	431.222
205.10(a)(5)(v) to words before "* * * where the sole issue is one * * *. Also words after "* * * action for such refusal"	431.223
205.10(a)(5)(v) words after "* * * by the claimant in writing" to words before "* * * or where it is abandoned"	Deleted—unnecessary
205.10(a)(6)(i)(A) to words before "* * * and not one of incorrect grant * * *"	431.230 (a)(1) and (b)
205.10(a)(6)(i)(A) words after "* * * change in State or Federal Law * * * to words before "(ii) The agency shall * * *"	Deleted—unnecessary
205.10(a)(6)(ii)	431.230(a)(2)
205.10(a)(6)(iii) to words before "Unless a de novo * * *" and words after "* * * substantial evidence in the record	431.232
205.10(a)(6)(iii) words after "right to request a de novo hearing * * *" to words before "assistance shall not be * * *"	431.233
205.10(a)(7)	431.231
205.10(a) (8)-(10)	431.240
205.10(a)(11) to words before "in respect to title IV-C"	431.243
205.10(a)(11) words after "* * * in the conduct of the hearing	Not applicable to Medicaid
205.10(a)(12) to words before "* * * or in making a payment	431.241
205.10(a)(12) words after "* * * decision on eligibility * * *" to words before "(ii) Agency * * *"	Deleted—unnecessary
205.10(a)(12)(i), introductory paragraph, (A), and (B) first word and words after "* * * of financial or * * *" and before "or change"	431.241
205.10(a)(12)(ii)(B) words after "Amount" and before "* * * medical assistance * * *" and words after "* * * medical assistance"	Not applicable to Medicaid
205.10(a)(12)(ii)(C)	Not applicable to Medicaid
205.10(a)(13) to words before "(ii) At his * * *	431.242
205.10(a)(13)(i)	431.242(a)
205.10(a)(13)(ii)	Deleted—redundant
205.10(a)(13)(iii)	431.242(b)

Redesignation Table IV

Old Section in 45 CFR	New Section in 42 CFR
205.10(a)(13)(iv)	431.242(c)
205.10(a)(13)(v)	431.242(d)
205.10(a)(13)(vi)	431.242(e)
205.10(a) (14)-(16)	431.243
205.10(a)(17)	431.245
205.10(a)(18)	431.246
205.10(a)(19)	431.244
205.10(b) (1)-(2)	431.250
205.10(b)(3)	Deleted—[illegible]
205.10(b)(4)	431.250
205.30	431.15
205.50(a) words before "(A) The administration * * *"	431.301
205.50(a)(1)(i)(A) after words "such purposes include"	431.302 (a)-(c)
205.50(a)(1)(i)(B)	431.302(d)
205.50(a)(1)(i)(C)	Not applicable to Medicaid
205.50(a)(1)(ii)	431.303
205.50(a)(1)(iii)	431.306(c)
205.50(a)(2)	431.305(a)
205.50(a)(2)(i)	431.305(b)
205.50(a)(2)(ii)	431.306(b)
205.50(a)(2)(iii)	431.306(d)
205.50(a)(2)(iv)	431.306(f)
205.50(a)(2)(v)	431.306(e)
205.50(a)(3)	431.304
205.50(a)(4)	431.307
205.50(b)	431.301
205.50(c)	Not applicable to Medicaid
205.50(d)	Not applicable to Medicaid
205.60(a)(1)	431.17 (a)-(c)
205.60(a)(2)	431.16
205.60(b)	431.17(d)
205.70(a)	431.18(a)
205.70(b) (1)-(2)	431.18(b)
205.70(c) words before "* * * and will establish * * *"	431.18 (c) and [illegible]
205.70(c) words after "* * * or to prepare for a fair hearing * * *"	431.18(f)
205.100(a)(1) (i)-(iii)	431.10(b)
205.100(a)(2)(i)	431.10(c)
205.100(a)(2)(ii)	431.10(d)
205.100(b)	431.10(e)
205.101(c)(1)	431.11(b)
205.101(c) (2)-(3)	431.11(c)
205.101(c)(4)	431.11(d)
205.120(a)	431.50(b)
205.120(b)	431.50(c)
205.130(a)(1)	[illegible]
205.130(a)(2)	[illegible]
205.145 to words before "Under this requirement * * *"	431.120(a)
205.145 words after "* * * in accord with applicable Federal requirements" and (a)	[illegible]
205.145(b)	[illegible]
205.145(c)	[illegible]
205.150(a)(1)	[illegible] through [illegible]
205.150(a)(1)(ii) words before "(The estimated costs are included * * *"	[illegible]
205.150(a)(1)(ii) words after "* * * activities with justification for each * * *" to words before "(iii)"	[illegible]
205.150(a)(1)(iii)	[illegible]
205.150(a)(1)(iv)	[illegible]
205.150(a)(2)	[illegible]
205.150(b)(1)	[illegible]
205.150(b)(2)	[illegible]
205.150(b)(3)	[illegible]
205.150(b)(4)	[illegible]
205.150(b)(5)	[illegible]
205.150(b)(6)	[illegible]
205.160(a)	[illegible]
205.160(a) (1) through (3)	[illegible]
205.160(b) (1) and (2), first sentence	[illegible]
205.160(b)(2), second and third sentences	[illegible]
205.160(b)(3)	[illegible]
205.160(c)(1)	[illegible]
205.160(c)(2)	[illegible]
205.160(c)(3)	[illegible]
205.170	Deleted—[illegible]

Old Section in 45 CFR	New Section in 42 CFR
206.10(a)(1)(i)	435.906 and 436.901.
206.10(a)(1)(ii)	435.907 and 436.901.
206.10(a)(1)(iii)	435.908 and 436.901.
206.10(a)(1)(iv) (A) and (B)	435.909 and 436.909.
206.10(a)(1)(iv)(C)	435.907 and 436.901.
206.10(a)(1)(v) (A) and (C)	435.910 and 436.901.
206.10(a)(1)(v)(B)	Not applicable to Medicaid.
206.10(a)(2)(i)	435.905 and 436.901.
206.10(a)(2)(ii)	435.916(b) and 436.901.
206.10(a)(3)	435.911 and 436.901.
206.10(a)(4)	435.912 and 436.901.
206.10(a)(5)	435.930 and 436.901.
206.10(a)(6)(i)	Not applicable to Medicaid.
206.10(a)(6)(ii)	435.914 and 436.901.
206.10(a)(7)	435.919 and 436.901.
206.10(a)(8)	435.913 and 436.901.
206.10(a)(9) (i) and (ii)	435.916(c) and 436.901.
206.10(a)(9)(iii) words before "* * * and every 12 months * * *"	Not applicable to Medicaid.
206.10(a)(9)(iii) words after "* * * than every 6 months in AFDC * * *"	435.916(a) and 436.901.
206.10(a)(9)(iii) (A) and (B)	435.920 and 436.901.
206.10(a)(10)	435.902 and 436.901.
206.10(a)(11)	435.903 and 436.901.
206.10(a)(12)	435.904 and 436.901.
206.10(b)(1)	Redundant—430.1.
206.10(b)(2)	Redundant—435.907.
208.1(a)	441.101.
208.1(a)(1)	431.620.
208.1(a)(2)	441.102(a).
208.1(a)(2)(i), first sentence	441.102(b)(2).
208.1(a)(2)(i), second sentence	441.102(b)(1).
208.1(a)(2)(ii)	441.102(b)(4).
208.1(a)(2)(iii)	441.102(b)(3).
208.1(a)(2)(iv)	441.102(b)(5).
208.1(a)(3) and (4)	441.103.
208.1(a)(5) and (6)	441.105.
208.1(a)(7)	441.106.
208.1(b)	Not applicable to Medicaid.

DERIVATION TABLE

This list includes only new sections based on regulations existing before redesignation. Sections containing new material that is introductory or explanatory have not been included.

New Section in 42 CFR	Old Section in 45 CFR
431.10	205.100.
431.11	205.101.
431.15	205.30.
431.16	205.60(a)(2).
431.17	205.60(a) (1) and (b).
431.18	205.70.
431.50	205.120.
431.202	205.10(a) (Introductory paragraph).
431.205	205.10(a)(1).
431.206	205.10(a) (2) and (3).
431.210	205.10(a)(4)(i)(B).
431.211	205.10(a)(4)(i)(A).
431.213	205.10(a)(4)(ii).
431.214	205.10(a)(4)(iv).
431.220	205.10(a)(5).
431.221	205.10(a)(5) (i)-(iii).
431.222	205.10(a)(5)(iv).
431.223	205.10(a)(5)(v).
431.230	205.10(a)(6).
431.231	205.10(a)(7).
431.232	205.10(a)(6)(iii) (1st Sentence).
431.233	205.10(a)(6)(iii) (2nd Sentence).
431.240	205.10(a) (8)-(10).

Redesignation Table IV

New Section in 42 CFR	Old Section in 45 CFR
431.241	205.10(a)(12) (i) and (ii)(B).
431.242	205.10(a)(13).
431.243	205.10(a)(11) (1st Sentence)
431.244	205.10(a) (14), (15) and (16)
431.245	205.10(a)(17).
431.246	205.10(a)(18).
431.250	205.10(b).
431.301	205.50(a)(1)(i)(A) (1st Sentence) and 205.50 (b) and (c)
431.302	205.50(a)(1)(i)(A) (2nd Sentence).
431.303	205.50(a)(1)(ii).
431.304	205.50(a)(3).
431.305	205.50(a)(2)(i).
431.306	205.50(a)(2) (ii)-(v).
431.307	205.50(a)(4).
431.620	208.1(a)(1).
433.32	205.145.
433.33	205.130.
433.34	205.150.
433.35	205.160.
435.902	206.10(a)(10).
435.903	206.10(a)(11).
435.904	206.10(a)(12).
435.905	206.10(a)(2)(i).
435.906	206.10(a)(1) (Introductory paragraph).
435.907	206.10(a)(1)(ii) (words before "from the applicant")
435.908	206.10(a)(1)(ii) (words after "State agency") and (iii).
435.909	206.10(a)(1)(iv) (A) and (B).
435.910	206.10(a)(1)(v) (A) and (C).
435.911	206.10(a)(3).
435.912	206.10(a)(4).
435.913	206.10(a)(8).
435.914	206.10(a)(6).
435.916	206.10(a)(2)(ii) and 206.10(a)(9) (i)-(iii).
435.919	206.10(a)(7).
435.920	206.10(a)(9)(iii) (A) and (B).
435.930	206.10(a)(5).
436.901	206.10.
436.909	206.10(a)(1)(iv) (A) and (B).
441.101	208.1(a) (words before "(1) Having in effect * * *")
441.102	208.1(a)(2).
441.103	208.1(a) (3) and (4).
441.105	208.1(a) (5) and (6).
441.106	208.1(a)(7).

Redesignation Table V

At 45 FR 22935, Apr. 4, 1980, certain sections of regulations formerly appearing in Title 42 as Part 405 were redesignated as Part 489.

For the convenience of the user, the following tables show the relationship of the redesignated sections.

PART 456—UTILIZATION CONTROL

Old 42 CFR Part 405	New 42 CFR Part 489
405.602	489.10
405.603	489.12
405.604(a)(1)	489.15(b)
405.604(a)(2)	489.15(c)
405.604(b)	489.15(d)
405.604(c)(1)	489.16(a)
405.604(c)(2)	489.16(c)
405.604(c)(3)	489.16(b)(1) and (2)
405.604(d)	Deleted as outdated
405.605	489.2(b) & (c)
405.606(a)	489.11(a)
405.606(b)	489.11(b) & (c)
405.606(c)	489.53
405.607(a)	489.21(a)
405.607(b)	489.20(b)
405.607(c)	489.20(c)
405.608	489.30
405.609	489.31
405.610(a)	489.32
405.610(b)	489.22
405.612	489.21(b)
405.613	489.52
405.614	489.53
405.615	489.55
405.616	489.57
405.617	489.50
405.618	489.40
405.619	489.35
405.620(a)	489.41(c)
405.620(b)	489.41(a)
405.620(c)	489.41(b)
405.620(d)	Deleted as unnecessary
405.621	489.41(a)
405.622	489.42
405.625(a)	Superseded by 489.18(b), (c) and (d)
405.625(b)	Deleted because of change in policy
405.626(a)	489.18(a)(1)
405.626(b)	489.18(a)(2)
405.626(c)	489.18(a)(3)
405.626(d)	489.18(e)

DERIVATION TABLE

New 42 CFR Part 489	Old 42 CFR Part 405
489.1	New
489.2(a)	405.601, 1st sentence
489.2(b) and (c)	405.605
489.3	New
489.10	405.602
489.11(a)	405.606(a)
489.11(b) and (c)	405.606(b)
489.12	405.603
489.13	405.606
489.15(a)	405.604, introductory paragraph
489.15(b)	405.604(a)(1)
489.15(c)	405.604(a)(2)
489.15(d)	405.604(b)
489.16(a)	405.604(c)(1)
489.16(b)(1) and (2)	405.604(c)(3)
489.16(c)	405.604(c)(2)
489.18(a)(1)	405.626(a)
489.18(a)(2)	405.626(b)
489.18(a)(3)	405.626(c)
489.18(a)(4)	405.626(d)
489.18(b)	405.625(b)
489.18(c) and (d)	405.625(a) with substantive change
489.18(e)	405.626(d)
489.20(a)	405.607(a)
489.20(b)	405.607(b)
489.20(c)	405.607(c)
489.21(a)	405.607(a)(1)
489.21(b)(1)	405.612(a)(2)
489.21(b)(2)	405.612(a)(3)
489.21(b)(3)	405.612(a)(4)
489.21(b)(4), 1st sentence	405.607(a)(2) and 405.612
489.21(b)(4), 2nd sentence	405.612(b)
489.21(c)	405.607(a)(3)
489.21(d)	405.607(a)(4)
489.22	405.610(b)
489.30	405.608
489.31	405.609
489.32	405.610(a)
489.35	405.619
489.40	405.618
489.41(a)	405.620(b) and 405.621
489.41(b)	405.620(c)
489.41(c)	405.620(a)
489.42	405.622
489.50	405.617
489.52(a)	405.613(a), 1st and 2nd sentences
489.52(b)(1)	405.613(a), 3rd and 4th sentences

DERIVATION TABLE—Continued

New 42 CFR Part 489	Old 42 CFR Part 405
489.52(b)(2)	405.613(b), except for last sentence
489.52(b)(3)	405.613(c)
489.52(c)	405.613(a), last two sentences and 405.613(b), last sentence
489.53	405.614
489.55	405.615
489.57	405.616

Redesignation Table VI

The following table, published at 45 FR 24882, Apr. 11, 1980, reflects corrections to Redesignation Table IV, published at 44 FR 17927, Mar. 23, 1979.

CORRECTED REDESIGNATION TABLE

New section	Old section
448.2(b)	435.401(c)(1).
448.3(c)(1)(iv)	435.840.
448.3(c)(3)(ii)	435.831(a) (2), (3), 435.845(d), (e).
449.33(a)(5)	431.610(g).
449.33(b)(2)	431.610(h).
450.25	431.800.
450.30(a)(2) (words "provide for . . .")	447.251.
450.30(a)(3) (introductory paragraph, words after "cost-related basis")	447.301.
450.30(a)(3) (words "provide for").	447.251.
450.30(a)(4) (words "provide for")	447.251.
450.30(a)(10)	447.371.
450.30(b)(4)(i)	447.351.
450.30(b)(4)(ii), and (iii)	447.352.
450.30(b)(5)	447.321, 447.325.
450.100	431.610 except (g) & (h).
450.310	455.300.

CORRECTED DERIVATION TABLE

New section	Old section
431.610 except (g) & (h)	450.100.
431.610(g)	449.33(a)(5).
431.610(h)	449.33(b)(2).
431.800	450.25.
435.110	448.1(b)(1)(i).
435.401	448.2(a) & (b).
435.831	448.1(a)(2)(ii), (b)(3)(v), (5)(iv), (c)(2), (3), (4).
447.251 (covers the previous State Plan requirement in 450.30(a)(2), hospitals, (a)(3), long term care services, and (a)(4), upper limits for all services.	450.30(a)(2), 450.30(a)(3), 450.30(a)(4).
447.301	450.30(a)(3), Introductory paragraph, words after "cost-related basis," and 450.30(a)(3)(iv).
447.325	450.30(b)(5).
447.351	450.30(b)(5)(i).
447.352	450.30(b)(4)(ii) and (iii).
447.361	450.30(b)(7).
447.371	450.30(a)(10).

Redesignation Table VII

At 45 FR 42179, June 23, 1980, certain sections of regulations formerly in Title 42 as Part 405 were redesignated as Part 421.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	NPRM section	New section
405.651(a), 405.652, 405.653	419.13	421.104
405.651(b)	419.3(c)	421.5(c)
405.651(c)	419.3(b)	421.5(b)
405.651(d)	419.3(a)	421.5(a)
405.654	419.12	421.103
405.655	419.14	421.105
405.656	419.13	421.104
405.660	419.25	421.110
405.662, 405.663	419.30	421.126
405.670, 405.677, 405.678	419.40	421.200
405.671	419.2	421.3
405.672	419.3(a)	421.5(a)
405.673	419.41	421.202
405.675	419.44	421.204
405.676	419.45	421.205

Redesignation Table VIII

At 46 FR 55696, November 12, 1981, certain sections of regulations formerly in Title 20 as Part 422 were redesignated and transferred to Title 42 as Part 401.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	NPRM section	New section
20 CFR 422.401	42 CFR 401.101(a)(2)	
422.402	401.102	
422.406	401.106	
422.408	401.108	
422.410	401.110	
422.412	401.112	
422.416	401.116	
422.418	401.118	
422.420	401.120	
422.426	401.126	
422.428	401.128	
422.430	401.130	
422.432	401.132	
422.433	401.133	
422.434	401.134	
422.435	401.135	
422.436	401.136	
422.440	401.140	
422.444	401.144	
422.448	401.148	
422.452	401.152	

Redesignation Table IX

At 48 FR 12534, Mar. 25, 1983, certain sections of regulations formerly appearing in Title 42 as Part 405 were redesignated.

For the convenience of the user, the following table shows the disposition of the redesignated sections.

Old section	New section
405.101(a)	409.3
405.101(b)	Deleted
405.102	408.10
405.103	408.11
405.104	408.13
405.105	408.12
405.106 (a) & (b)	408.20
405.106 (c) & (c)(1)	408.21
405.106(c)(2)	408.25
405.106(c)(3)	Deleted as unnecessary. § 405.210 clearly applies only to individuals already entitled to Hospital Insurance. Reference to § 405.106 must be deleted from § 405.205
405.106(d)	408.22
405.110(a)	Deleted as inaccurate and unnecessary
405.110(a) (1) & (2)	409.61(a)(1)
405.110(b)	409.3
405.110(c)(1)	Deleted as outdated
405.110(c)(2)	Deleted as redundant
405.110(d)	409.62(a)
405.111 Uncoded introduction	Deleted as unnecessary
405.111(a)	409.63(b)
405.111(b)	Deleted as outdated
405.111 (c) & (d)	409.63(a)
405.112	409.64
405.113	409.80
405.114	409.87
405.115	409.82
405.116	409.10
405.116(a)	409.10
405.116(b)	409.11
405.116(c)	409.12
405.116(d)(1)	409.13
405.116(d)(2)	409.14
405.116(e)	409.16
405.116(f)	409.15
405.116(g) and (h)	409.18
405.117	409.89
405.118(a) language through "paragraph (c) of this section"	409.65(b)
405.118(a) remaining language	409.65(a)
405.118(b)	409.65(c)
405.118(c)	409.65(d)
405.118(d)	409.65(e)
405.119	409.66
405.120(a)(1) words "he was an inpatient for not less than 3 consecutive days"	409.30(a)
405.120(a)(1) all other words	Deleted because merely cross-reference or duplicative of content of § 409.30
405.120(a)(2) First 2 sentences	Deleted as outdated
405.120(a)(2) Last sentence	Deleted as unnecessary; the cited § 405.152 takes care of the matter
405.120(b)(1)	Deleted because 100-day limitation is contained in § 409.61(b)
405.120(b)(2)	409.32
405.120(b)(3)	Deleted because the essentials of the cited sections are incorporated in § 409.31
405.120(c)	[illegible]
405.120(d)(2) Words through "the 3rd and final October 30, 1972"	Deleted as unnecessary. Since (d)(1), which dealt with admissions before 10/30/72, was deleted, there is only one set of requirements
405.120(d)(2) remaining words through (d)(2)	[illegible]
405.120(d)(3) Words through the parenthetical statement	Deleted as unnecessary (a calendar day is a calendar day)
405.120(d)(3) remaining words	[illegible]
405.121(a) deductible and coinsurance amounts	[illegible]
405.122	[illegible]
405.123	[illegible]
405.124	[illegible]
405.125	[illegible]
405.126 Uncoded introduction	Deleted as unnecessary
405.126 (a) & (b)	[illegible]
405.127(a)	[illegible]
405.127(b)	[illegible]
405.127 (c) & (d)	[illegible]
405.128	[illegible]
405.128a	[illegible]
405.130	[illegible]
405.131 Uncoded introduction (and specifics taken from 405.236)	[illegible]
405.131(a)-(f)	[illegible]

Old section	New section
405.133	Deleted because Section 941 of Pub. L. 96-499 revoked the presumed coverage provisions of the Act.
405.151	409.69.
405.161	409.68.
405.180	408.30.
405.181	408.31
430.1	400.200 and 400.203

Redesignation Table X

At 50 FR 1345, Jan. 10, 1985, certain sections of regulations formerly appearing in Title 42, Part 405, Subpart T were redesignated as Part 417.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.2002	417.202
405.2003	417.203
405.2004	417.204
405.2005	417.205
405.2007	417.207
405.2020	417.220
405.2021	417.221
405.2022	417.222
405.2023	417.223
405.2024	417.224
405.2025	417.225
405.2028	417.228
405.2029	417.229
405.2030	417.230
405.2031	417.231
405.2032	417.232
405.2033	417.233
405.2034	417.234
405.2035	417.235
405.2036	417.236
405.2037	417.237
405.2038	417.238
405.2039	417.239
405.2040	417.240
405.2041	417.241
405.2042	417.242
405.2043	417.243
405.2044	417.244
405.2045	417.245
405.2046	417.246
405.2047	417.247
405.2049	417.249
405.2050	417.250
405.2051	417.251
405.2052	417.252
405.2053	417.253
405.2054	417.254
405.2056	417.256
405.2058	417.258
405.2059	417.259
405.2060	417.260
405.2061	417.261
405.2062	417.262
405.2063	417.263
405.2065	417.265
405.2066	417.266
405.2067	417.267
405.2068	417.268
405.2069	417.269
405.2070	417.270
405.2071	417.271
405.2072	417.272
405.2073	417.273
405.2074	417.274
405.2075	417.275
405.2076	417.276
405.2077	417.277
405.2078	417.278
405.2079	417.279
405.2080	417.280
405.2081	417.281
405.2082	417.282
405.2083	417.283
405.2084	417.284
405.2085	417.285
405.2086	417.286
405.2087	417.287
405.2088	417.288
405.2089	417.289
405.2090	417.290
405.2091	417.291
405.2092	417.292
405.2093	[1] 417.800
405.2094	417.802
405.2095	417.804
405.2096	417.806
405.2097	417.808
405.2098	417.810

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[1] Section 417.801 was redesignated from 42 CFR 405.692.

Redesignation Table XI

At 50 FR 12741, Mar. 29, 1985, certain sections of regulations formerly appearing in Title 42 as Part 405 were redesignated as Part 412.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old paragraph	New paragraph or section
405.470(a)(1)	412.1(a)
405.470(a)(2)	412.1(b)
405.470(b)(1)	412.2(a)
405.470(b)(2)	412.2(b)
405.470(b)(3)	412.2(c)
405.470(b)(4)	412.2(d)
405.470(b)(5)	412.2(e)
405.470(c)(1)	412.4(a)
405.470(c)(2)	412.4(b)
405.470(c)(3)	412.4(c)
405.470(c)(4)	412.4(d)
405.470(d)(1)	412.6(a)
405.470(d)(2)	412.6(b)
405.470(e)(1)	412.8(a)
405.470(e)(2)	412.8(b)
405.471(a)(1)	412.20(a)
405.471(a)(2)	412.20(b)
405.471(b)(1)	412.22(a)
405.471(b)(2)	412.22(b)
405.471(b)(3)	412.22(c)
405.471(c)(1)	412.23(a)
405.471(c)(2)	412.23(b)
405.471(c)(3)	412.23(c)
405.471(c)(4)(i)	412.25(a)
405.471(c)(4)(ii)	412.27
405.471(c)(4)(iii)	412.29
405.471(c)(4)(iv)	412.32
405.471(c)(5)	412.23(d)
405.471(c)(6)	412.23(e)
405.471(c)(7)	412.23(f)
405.471(c)(8)	412.23(g)
405.471(d)	412.23(b)(8)
405.471(e)(1)	412.30(a)
405.471(e)(2)	412.30(b)
405.471(f)	412.25(b)
405.472(a)(1)	412.40(a)
405.472(a)(2)	412.40(b)
405.471(b)(1)	412.42(a)(2)
405.472(b)(1)(i)	412.42(a)(2)(i) and 412.42(b)
405.472(b)(1)(ii)	412.42(b)(2)
405.472(b)(1)(iii)	412.42(c)
405.472(b)(1)(iv)	412.42(d)
405.472(b)(1)(v)	412.42(e)
405.472(b)(1)(vi)	412.42(f)
405.472(b)(2)	412.42(g)
405.472(b)(3)	412.42(a)(1)
405.472(c)	412.44
405.472(d)(1)	412.45
405.472(d)(2)	412.46
405.472(e)	412.48
405.472(f)	412.50
405.472(g)	412.52
405.473(a)(1)	412.60(a)
405.473(a)(2)	412.60(b)
405.473(a)(3)	412.60(c)
405.473(a)(4)	412.60(d)
405.473(b)(1)	412.62(a)
405.473(b)(2)	412.62(b)
405.473(b)(3)	412.62(c)
405.473(b)(4)	412.62(d)
405.473(b)(5)	412.62(e)
405.470(b)(6)	412.62(f)
405.473(b)(7)	412.62(g)
405.473(b)(8)	412.62(h)
405.473(b)(9)	412.62(i)
405.473(b)(10)	412.62(j)
405.473(b)(11)	412.62(k)
405.473(c)(1)	412.63(a)
405.473(c)(2)	412.63(b)
405.473(c)(3)	412.63(c)
405.473(c)(4)	412.63(d)
405.473(c)(5)	412.63(e)
405.473(c)(6)	412.63(f)
405.473(c)(7)	412.63(g)
405.474(a)(1)	412.70(a)
405.474(a)(2)	412.70(b)
405.474(a)(3)	412.70(c)
405.474(a)(4)	412.70(d)
405.474(b)(1)	412.71(a)
405.474(b)(2)(i)	412.71(b)
405.474(b)(2)(ii)	412.71(c)
405.474(b)(3)(i)	412.71(d)
405.474(b)(3)(i)(A)	412.72(a)(1)
405.474(b)(3)(i)(B)	412.72(a)(2)
405.474(b)(3)(i)(C)(1)	412.72(a)(3)(i)
405.474(b)(3)(i)(C)(2)	412.72(a)(3)(ii)
405.474(b)(3)(i)(D)	412.72(a)(4)
405.474(b)(3)(i)(E)	412.72(a)(5)
405.474(b)(3)(ii)	412.72(b)
405.474(b)(4)	412.73(a)
405.474(b)(5)	412.73(b)
405.474(b)(6)	412.73(c)
405.474(b)(7)	412.73(d)
405.474(b)(8)	412.73(e)
405.474(c)(1)	412.74(a)
405.474(c)(2)	412.74(b)
405.474(d)	412.76
405.475(a)(1)	412.80(a)
405.475(a)(2)	412.80(c)
405.475(b)	412.80(d)
405.475(c)(1)	412.82(a)
405.475(c)(2)	412.82(b)
405.475(c)(3)	412.82(c)
405.475(c)(4)	412.82(d)
405.475(d)(1)	412.84(a)
405.475(d)(2)	412.84(b)

Redesignation Table XI

Old paragraph	New paragraph or section
405.475(d)(3)	412.84(c)
405.475(d)(4)	412.84(d)
405.475(d)(5)	412.84(e)
405.475(d)(6)	412.84(f)
405.475(e)	412.80(e)
405.476(a)	412.90
405.476(b)(1)	412.92(b)(1) and (b)(2)
405.476(b)(2)	Removed as duplicative of § 405.473(b)(6)
405.476(b)(3)(i)	412.92(b)(4)
405.476(b)(3)(ii)	412.92(a)
405.476(b)(4)&(b)(5)	412.92(c)
405.476(b)(6)	412.92(b)(3)
405.476(c)	412.92(d)
405.476(d)	412.92(e)
405.476(e)	412.98
405.476(f)(1)	412.94(a)
405.476(f)(2)	412.94(b)
405.476(g)(1)	412.96(a)
405.476(g)(1)(i)&(ii)	412.96(b)
405.476(g)(1)(iii)	412.96(c)
405.476(g)(2)(i)	412.96(d)
405.476(g)(2)(ii)	412.96(e)
405.476(g)(3)	412.96(f)
405.476(h)	412.100
405.476(i)(1)	412.102(a)
405.476(i)(2)	412.102(b)
405.476(j)(1)	412.104(a)
405.476(j)(2)	412.104(b)
405.477(a)	412.110
405.477(b)	412.112
405.477(c)	412.113
405.477(d)(1)&(d)(2)(i)	412.115
405.477(d)(2)(ii)	412.118(a)
405.477(d)(2)(iii)	412.118(b)
405.477(d)(2)(iv)	412.118(c)
405.477(d)(2)(v)	412.118(d)
405.477(d)(2)(vi)(A)	412.118(e)
405.477(d)(2)(vi)(B)	412.118(e)
405.477(d)(2)(vi)(C)	412.118(f)
405.477(e)(1)	412.120(a)
405.477(e)(2)	412.120(b)
405.477(e)(3)	412.120(c)
405.477(f)	412.125

Redesignation Table XII

At 51 FR 22040, June 17, 1986, §§ 405.1011—405.1042 (Subpart J), formerly appearing in Title 42, Part 405, were redesignated as Part 482 of Title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old Part 405	New Part 482
405.1011	482.2
405.1020	482.11
405.1021(a)-(d)	482.12
405.1021(e)	482.12(a)
405.1021(f) & (g)	482.12(b)
405.1021(h)	482.12(c)
405.1021(i)	482.41
405.1021(j)	482.12(d)
405.1022	482.41 and 482.42
405.1023	482.22
405.1024 except (d)	482.23
405.1024(d)	482.51
405.1025	482.28
405.1026	482.24
405.1027	482.25
405.1028	482.27
405.1029	482.26
405.1030	Deleted
405.1031(a)	482.51
405.1031(b)	482.52
405.1031(c)	Deleted as duplicative of 482.22
405.1031(d)	482.56
405.1032	482.54
405.1033	482.12(f)
405.1034	Deleted. Provision included as part of 482.21(b)
405.1035	482.30
405.1036	482.60
405.1037	482.61
405.1038	482.62
405.1039	Deleted. Provisions removed by law.
405.1040	Deleted. Provisions removed by law.
405.1041	482.66
405.1042	482.30

Redesignation Table XIII

At 51 FR 34790, Sept. 30, 1986, certain sections of regulations formerly appearing in Title 42, Part 405, Subpart D were redesignated as Part 413 of Title 42. For the convenience of the user, the following table shows the relationship of the redesignated sections.

REDESIGNATION TABLE FOR 42 CFR 405.401 THROUGH 405.463

Old section	New section
405.401	413.1
405.402	413.5
405.403	413.50
405.405	413.60
405.406	413.20
405.414	413.130
405.415	413.134
405.416	413.139
405.417	413.144
405.418	413.149
405.419	413.153
405.420	413.80
405.421	413.85
405.422	413.90
405.424	413.94
405.425	413.98
405.426	413.102
405.427	413.17
405.429	413.157
405.432	413.106
405.433	413.110
405.434	413.114
405.435	413.161
405.436	413.178
405.438	[1]
405.439	413.170
405.440	[1]
405.441	413.174
405.451	413.9
405.452	413.53
405.453	413.24
405.454	413.64
405.455	413.13
405.456	413.74
405.457	413.56
405.460	413.30
405.461	413.35
405.463	413.40

[1] Deleted.

Redesignation Table XIV

At 51 FR 41335, Nov. 14, 1986, certain sections of regulations formerly appearing in Title 42, Part 405, Subpart B were redesignated as Part 410 of Title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old sec.	New sec.
405.230	410.150
405.231(a)	410.10(a), 410.20
405.231(b)	410.10(b) 410.26
405.231(c)	410.10(c), 410.27
405.231(d)	410.10(f), 410.32
405.231(e)	410.10(g), 410.34
405.231(f)	410.10(h), 410.36(a)
405.231(g)	410.10(i), 410.38
405.231(h)	410.10(h), 410.36(b)
405.231(i)	410.10(h), 410.36(c)
405.231(j)	410.10(j), 410.40
405.231(k)	410.10(d), 410.28
405.231(l)	410.10(m), 410.60
405.231(m)	410.10(m), 410.62
405.231(n)	410.10(k), 410.45
405.231(o)	410.10(l), 410.50
405.231(p)	410.10(l), 410.52
405.231(a)	410.10(o), 410.55
405.232(b)	Removed as outdated.
405.232(b)	410.32
405.232(c)	410.29
405.232(d)	410.28
405.232(e)	410.60
405.232(f), (g), and (h).	410.32 and 410.34
405.232(i)	410.40
405.232(j)	410.62
405.232a(a)(1)	410.20
405.232a(a)(2)	410.20(b) and 410.24
405.232a(a)(3)	410.20(b) and 410.25
405.232a(a)(4)	410.20(b) and 410.23
405.232a(a)(5)	410.20(b) and 410.22
405.232a(b)	410.14
405.232b	410.22
405.232c	410.23
405.233	Removed as inconsistent with current law which no longer limits the home health visits.
405.234	Removed as duplicative of § 409.42(b) and (d)
405.235	Removed as duplicative of § 409.42(e)
405.236	Removed as duplicative of 409.40
405.237	Removed as duplicative of 409.41
405.238	Removed as duplicative of 409.43
405.239	Removed as inconsistent with current law which no longer limits the number of home health visits.
405.240	410.152
405.241	410.152(a)(2)(iii)
405.243	410.155
405.244a	410.152(a)(1)(i)
405.244(b)	410.152(a)(1)(ii)
405.244(c)	Removed as inconsistent with current law which no longer provides for 100 percent payment for radiology and pathology services.
405.244-1(a)	410.163
405.244-1(b)	410.152(i)(1)
405.244-1(c)	410.152(i)(2)
405.245	410.160
405.246	410.161
405.249	410.168
405.250	410.170
405.250-2	410.165
405.251	Removed as duplicative of Subpart P of Part 405.
405.252	410.175
405.260	410.100
405.261	410.102
405.262	410.105

Redesignation Table XV

At 52 FR 22446, June 12, 1987, certain sections of regulations appearing in Title 42, Part 405, Subparts F and O were redesignated as Part 498 of Title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.640	498.20(a)(2)
405.685	405.1902(b)
405.1501(a)	Removed as duplicative of § 405.1502.
405.1501(b), (c), and (e)	498.5
405.1501(d)	498.3(e)
405.1502	498.3(b)
405.1503	498.20(a)
405.1504	498.20(b)
405.1505	498.3(c)
405.1510	498.22(a)
405.1511(a)	498.22(c)
405.1511(b)	498.22(b)
405.1512	498.22(b)(2)
405.1513	498.23
405.1514	498.24
405.1515	498.24
405.1516	498.25(a)
405.1517	498.25(b)
405.1518	498.22(d)
405.1519	498.30
405.1520	498.32(a)
405.1521	498.32(b)
405.1530	Removed as duplicative of § 405.1531.
405.1531	498.40
405.1532	498.42
405.1533	498.44
405.1534	498.45
405.1535	498.47
405.1536	498.48
405.1537	498.49
405.1538	498.50
405.1539	498.50
405.1540	498.52
405.1541	498.53
405.1542	498.56
405.1543	498.54
405.1544	498.58
405.1545	498.60
405.1546	498.61
405.1547	498.62
405.1548	498.63
405.1549	498.64
405.1550	498.66
405.1551	498.68
405.1552	498.69
405.1553	498.70
405.1554	498.71
405.1555	498.71
405.1556	498.72
405.1557	498.74
405.1558	498.74
405.1559	498.76
405.1560	498.78
405.1561	498.80
405.1562	498.82
405.1563	498.83
405.1564	498.85
405.1565	498.86
405.1566	498.88
405.1567	498.90
405.1568	498.83
405.1569	498.95
405.1570	498.100
405.1571	498.102
405.1572 and 405.1571(c)	498.103
405.1590	498.10
405.1591	498.11
405.1592	498.13
405.1593	498.15
405.1594	498.11(b)
405.1595	498.17

Redesignation Table XVI

At 52 FR 36746, Sept. 30, 1987, regulations appearing in Title 42, Part 110 were redesignated as Part 417, Subpart A of Title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

REDESIGNATION TABLE FOR 42 CFR PART 417, SUBPART A

Old section	New section
110.101	417.100
110.102	417.101
110.103	417.102
110.104	417.103
110.105	417.104
110.106	417.105
110.107	417.106
110.108	417.107
110.109	417.108
110.110	417.109
110.201	417.110
110.202	417.111
110.203	417.112
110.204	417.113
110.205	417.114
110.206	417.115
110.207	417.116
110.208	417.117
110.209	417.118
110.210	417.119
110.401	417.120
110.402	417.121
110.403	417.122
110.404	417.123
110.405	417.124
110.406	417.125
110.407	417.126
110.501	417.130
110.502	417.131
110.503	417.132
110.504	417.133
110.505	417.134
110.506	417.135
110.507	417.136
110.508	417.137
110.601	417.140
110.602	417.141
110.603	417.142
110.604	417.143
110.605	417.144
110.801	417.150
110.802	417.151
110.803	417.152
110.804	417.153
110.805	417.154
110.806	417.155
110.807	417.156
110.808	417.157
110.809	417.158
110.810	417.159
110.901	417.160
110.902	417.161
110.903	417.162
110.904	417.163
110.905	417.164
110.906	417.165
110.907	417.166
110.1001	417.170
110.1002	417.171
110.1003	417.172
110.1004	417.173
110.1005	417.174
110.1006	417.175
110.1007	417.176
110.1008	417.177
110.1009	417.178
110.1010	417.179
110.1011	417.180

Redesignation Table XVII

At 52 FR 48114, Dec. 18, 1988, regulations appearing in Title 42, Part 405 were redesignated as Part 408 of Title 42. The redesignation table was correctly published at 53 FR 4158, Feb. 12, 1988.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

REDESIGNATION TABLE—42 CFR PART 405, SUBPART I

Old section	New section
405.901	408.2
405.902(a)	Deleted as unnecessary
405.902 (a)(1) and (a)(2)	408.20(b)
405.902(b)	408.22
405.902(b)(1)	408.24
Examples	408.26
405.902(c)	408.27
405.903 (a)	408.4(a)
405.903(b), first sentence	408.100
405.903(b), rest of the paragraph	408.4(b)
405.904, uncoded introduction	408.6(a)(1) and 408.8(c)
405.904(a)	408.42 and 408.43
405.904(b)	408.44
405.904(c)	408.42
405.904(d)	408.6(c)
405.904(e)	408.6(b)(3) and 408.60(a)
405.906	408.4(c)
405.908 uncoded introduction	408.60(a)
405.908 (a)–(c)	408.60(d)
405.911(a), first & third sentences	408.40(a)
405.911(a), second sentence	408.40(c)
405.911(b)	408.40(b)
405.911(c)	Deleted as duplicative and unnecessary
405.912(a), except second parenthetical statement	408.46(a)
405.912(a), parenthetical statement	408.3
405.912(b)	408.46(b)
405.913(a), first sentence	408.46(a)(2)
405.913(a), second sentence	408.47(a)(1)
405.913(a), third sentence	408.47(b)(2)
405.913 (b) & (c)	408.3 and 408.47(a)
Example	408.47(c)
405.913(d)	408.47 (a)(2) & (b)(2)
405.914(a)	408.50(b)(1)
Examples	Deleted as duplicative of examples in 405.956(a)
405.914(b)	408.50(b)(2)
405.914(c)	408.50(b)(3)
405.9 (a), first sentence	408.10(a)
405.915(a), second sentence	Deleted as duplicative of 405.912
405.915 (b)(1) & (2)	408.10 (b) and (b)(1)
405.915(b)(3)	408.10(b)(2)
405.916	408.45
405.920, uncoded introduction	408.6(b)(3)
405.920(a), first and second sentences	408.62
405.920(a), third and fourth sentences	408.6(a)(1)
405.920 (b) & (c)	408.62
405.920(d)	408.65
405.920(e)	408.71
405.921(a)	408.60(b)
405.921(b)	Deleted as inconsistent with current practice
405.927	408.8(a)
405.928	408.8(b)
405.929	408.8(d)
405.936, text	408.70
405.936, Example	Deleted as unnecessary
405.940(a)	408.80 (a) & (b)
405.940 (b) & (c)	408.80(c)
405.941(a)	408.82(a)
405.941(b)	408.82(b)
405.941(c), first sentence	408.82(e)
405.941(c), rest of paragraph	408.80(b)
405.941(d), first & second sentences	408.82(c)
405.941(d), rest of paragraph except last sentence	408.82(d)
405.941(d), sentence	Deleted as inappropriate in the context of group billing
405.941(e)	408.84(c)
405.941(f), first sentence	408.84(d)
405.941(f), rest of paragraph	408.88(a)
Example	408.88(b)
405.942 (revised per change practice)	408.84(b)
405.946(a)	408.84(a)
405.946(a), last sentence, and (b)	Deleted as duplicative of 405.841(d)
405.947(a)	408.92
405.947(b)	408.92(b)(2)
405.948(a)	408.86(a)
405.948(b)	408.86(b)
405.948(c)	408.86(c)
405.949	408.90
405.956(a)	408.50(a)
405.956(a), Examples	408.50(c)

REDESIGNATION TABLE—42 CFR PART 405, SUBPART I—Continued

Old section	New section
405.956(b) (revised to reflect simplified practice).	408.68(b).
405.957(a)	408.68(b).
405.957(b)	408.100(b).
405.958(a)	Deleted as inconsistent with 405.958(b).
405.958(b)	408.68(a).
405.959(a)	408.102(a).
405.959(b)(1)	408.102(b).
405.959(b)(2)	408.102(c).
405.959(c)	408.104.
405.960(a)	408.71.
405.960(b)	408.52.
405.962	408.110.
405.964	408.112.

Redesignation Table XVIII

At 53 FR 6632, Mar. 2, 1988, §§ 405.100—405.192 (Subpart A) and 405.1625—405.1697 (Subpart P), formerly appearing in Title 42, Part 405, were redesignated as Part 424 of Title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.100	424.10
405.150	409.100 and 424.51
405.152(a) (1) and (2)	424.101
405.152(a)(3)	424.103 introductory text
405.152(a)(4)	Removed as duplicative of 405.152(c)
405.152(a)(5)	424.103(a)(2)
405.152(a)(6)	Removed as duplicative of 405.1660
405.152(a)(7)	424.103(a)(1)
405.152(a)(8)	424.103(b)
405.152(b)	424.101
405.152 (c), (d), and (e)	424.104
405.153(a)	424.121(a)
405.153(a)(1)	424.122(a)
405.153(a)(2)	424.122(b)
405.153(a)(3)	424.122(d) and 424.123 (c) and (d)
405.153(b)	424.121(a)
405.153(b)(1)	424.123(a)
405.153(b)(2)	424.123(b)
405.153(b)(3)	424.123(c)
405.153(c)(1)	424.123(d) and 424.126
405.153(c)(2)	424.127
405.157	424.103(a) and 424.109(a)
405.158	424.109(b)
405.160(a) (1) and (2)	424.5
405.160(a)(3)	424.7
405.160(b)(1)	424.5(a)(5)
405.160(b)(2)	424.5(a)(4), 424.11, 424.14
405.160(b)(3)	424.14
405.160(b)(4)	424.7
405.160(c)	Removed as no longer pertinent. Inpatient services in TB hospitals are no longer included in the statute
405.162	424.7(a)
405.163	424.7(b)
405.165(a)	424.5(a)(5)
405.165(b)	424.5(a)(4), 424.11, 424.20
405.165(c)	424.7
405.166	424.7(a)
405.167	424.7(b)
405.170(a)	424.5(a)(5)
405.170(b)	424.5(a)(4), 424.11, 424.22
405.170(c)	424.5(a)(1)
405.191(a)	424.103(a)(4)
405.191(b)	Removed as unnecessary
405.191(b)(1)	424.103(b)
405.191(b)(2)	424.103(b)
405.191(b)(3)	424.103(a)(3)
405.191(b)(4) 1st sentence	Removed as poor example
405.191(b)(4) 2nd sentence	424.102(a)
405.191(b)(5)	424.102(b)
405.192(a)	424.106(a)
405.192(b)	Removed as unnecessary
405.192(b) (1)-(3)	424.106(b)
405.192(b)(4)	424.106(c)
405.192(c)	424.106(d)
405.192(d)(1)	Removed as inconsistent with definition of emergency
405.192(d)(2)	Removed as redundant with 405.192(c)
405.1625(a)	424.10(a)
405.1625(b)	424.11(a)
405.1625(c)	424.11(b)
405.1625(d)	424.11(c)
405.1625(e)	424.11(d)
405.1627 (a)(1)-(a)(3)	424.13(a)
405.1627(b)	424.13(b)
405.1627(c)	424.13(c)
405.1627(d)	424.13(d)
405.1627(e)(1)	424.13(d)
405.1627(e)(2)	424.13(e)
405.1627(e)(3)	424.13(f)
405.1627(e)(4)	424.13(g)
405.1629 Undesignated portion	424.14 (a) and (d)
405.1629 (a) and (b)	424.14 (b) and (c)
405.1629(c)	Removed as no longer pertinent (See comment on § 405.160(c))
405.1630	424.16
405.1632(a)	424.20, introductory statement
405.1632(b)	424.20(a)
405.1632(c)	424.20(b)
405.1632(d)	424.20(c)
405.1632(e) (1) and (2)	424.20(d)
405.1632(e)(3)	424.20(f)
405.1632(e)(4)	424.20(g)
405.1632(f)	424.20(e)
405.1633	424.22
405.1634(a)(1)	424.24(a)
405.1634(a)(2)	424.24(c)(4)
405.1634(a)(3)	Removed as duplicative of 405.1625(c)
405.1634(a)(4)	424.24(c)(3)
405.1634(a)(5)	424.24(c)(2)
405.1634(b)	424.24(c)(1) and 424.25
405.1634(c)	424.24(d)
405.1635	424.27

Old section	New section
405.1660 (a) and (b)	Removed as duplicative of other content.
405.1660(c)	424.5(a)(5).
405.1662(a) 1st sentence	405.207 and 406.7
405.1662(a) 2nd and 3rd sentences.	424.32(a).
405.1662(a) last sentence	Removed as unnecessary.
405.1662(b) list of forms	405.207 and 406.7.
405.1662(b) narrative	Removed as duplicative of 405.205 and 406.6.
405.1662(c)	424.32(b).
405.1662(d)	405.207, 406.7, and 424.32(c).
405.1663 Undesignated portion.	424.5(a)(5).
405.1663 (a) and (c)	424.40(b)(1).
405.1663 (b) and (d)	424.40(b)(2).
405.1664	424.36 and 424.37(b).
405.1665	424.37(a)
405.1666	424.36.
405.1667(a)	424.32.
405.1667(b) (1) and (2)	424.44
405.1667(b)(3)	424.45
405.1667(c)	Removed as outdated.
405.1668(a)	424.70.
405.1668 (b) and (c)	424.73.
405.1668(d)	424.74.
405.1672 (a) and (b)	424.53
405.1672(c)	424.34(a).
405.1672(d)	424.54
405.1672 (e) and (f)	424.73(b), 424.80(b), 424.86(b).
405.1674	424.34.
405.1675(a)(1)	424.55.
405.1675(a)(2)	424.56.
405.1675(b)	424.80(c).
405.1678	Removed as duplicative of 405.1675.
405.1679	424.36.
405.1680(a)	424.70(b).
405.1680(b)	424.71.
405.1680(c)	424.80(a).
405.1680(d)	424.80(b).
405.1681 (a)-(h)	424.82.
405.1681 (i) and (j)	424.83.
405.1681 (k) and (l)	424.84.
405.1682(a)	424.71.
405.1682(b)	424.90(a).
405.1682(c)	424.90(b).
405.1682(d)	424.90(c).
405.1683	424.62.
405.1684	424.64.
405.1685	424.66 (c) and (d).
405.1686	424.66(a).
405.1692	424.44
405.1693	424.45.
405.1694	424.44(c).
405.1695	424.350
405.1696	424.352
405.1697	424.354

Redesignation Table XIX

At 53 FR 23100, June 17, 1988, §§ 405.1901—405.1913 (Subpart S), formerly appearing in Title 42, Part 405, were redesignated as Part 488 of Title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

REDESIGNATION TABLE

Old section	New section
Part 405	Part 488
Subpart S	Subpart A
405.1901(a)	488.01
405.1901 (b) and (c)	488.03
405.1901(d)	488.05
405.1901(e)	488.06
405.1901(q)	488.08
405.1902(a)	488.10
405.1902(b)	488.11
405.1902(c)	488.12
405.1902(d)	488.14
405.1903	488.18
405.1904	488.20
405.1905	488.24
405.1906	488.26
405.1907	488.28
	Subpart B
405.1908	488.50
405.1909	488.52
405.1910	488.54
405.1911	488.56
405.1912	488.60
405.1913	488.64
	Subpart C
	488.100
	488.105
	488.110
	488.115

Derivation Table

At 51 FR 34764, Sept. 30, 1986, a document was published by the Department of Health and Human Services which established in Title 42 a new Chapter V, Office of Inspector General—Health Care, consisting of Parts 1001 through 1004. This document also removed Part 101 from Title 45. A second document at 51 FR 34786, Sept. 30, 1986 amended Title 42, Parts 412, 420, 455, 466, 474, and 489. The following derivation table identifies the sections of 42 CFR Chapter IV and 45 CFR Subtitle A from which the new 42 CFR Chapter V derives its content.

New Section	Source Section
	42 CFR Chapter IV
1001.1	420.1
1001.2	420.2
1001.3	420.3
1001.100	420.100
1001.101	420.101
1001.102	420.102
1001.103	420.103
1001.105	420.105
1001.107	420.107
1001.109	420.109
1001.114	420.114
1001.115	420.115
1001.122	420.122
1001.123	420.123
1001.124	420.124
1001.125	420.125
1001.126	420.126
1001.128	420.128
1001.130	420.130
1001.132	420.132
1001.134	420.134
1001.136	420.136
1001.201	489.54
1001.211	489.55
1001.221	489.57
1001.301	412.48(c), (d), and (e)
1002.1	455.1
1002.2	455.2
1002.3	455.106
1002.200	455.200
1002.203	455.203
1002.204	455.204
1002.205	455.205
1002.206	455.206
1002.207	455.207
1002.208	455.208
1002.210	455.210
1002.211	455.211
1002.212	455.212
1002.213	455.213
1002.214	455.214
1002.230	455.230
1002.232	455.234
1002.234	455.234
1002.301-1002.321	455.300
	45 CFR Subtitle A
1003.100	101.100
1003.101	101.101
	42 CFR Chapter IV
1003.102	101.102
1003.103	101.103
1003.104	101.104
1003.105	101.105
1003.106	101.106
1003.107	101.107
1003.108	101.108
1003.109	101.109
1003.110	101.110
1003.111	101.111
1003.112	101.112
1003.113	101.113
1003.114	101.114
1003.115	101.115
1003.116	101.116
1003.117	101.117
1003.118	101.118
1003.119	101.119
1003.120	101.120
1003.122	101.122
1003.123	101.123
1003.124	101.124
1003.125	101.125
1003.126	101.126
1003.127	101.127
1003.128	101.128
1003.129	101.129
1003.130	101.130
1003.131	101.131
1003.132	101.132
1003.133	101.133
	42 CFR Chapter IV
1004.1	474.0
1004.10	474.30
1004.20	474.32
1004.30	474.34
1004.40	474.36
1004.50	474.38
1004.60	474.39
1004.70	474.40
1004.80	474.41
1004.90	474.42
1004.100	474.52
1004.110	474.54
1004.120	474.56
1004.130	474.58

Table 1—20 CFR Part 405 List of CFR Sections Affected for 1973 to 1977

NOTE: At 42 FR 52826, September 30, 1977, regulations formerly appearing in Title 20 as Part 405 were redesignated and transferred into Title 42 as Part 405.

The following list of CFR sections affected contained in this table formerly appeared in Title 20 and is updated through September 30, 1977.

1973

20 CFR	38 FR Page
Chapter III	
405 Nomenclature changes	3597, 26718
Heading revised	13637
405.104 Added	17211
405.116 (g) added	17211
405.231 (g) and (h) revised	17211
405.316 (a) and (b) revised	13637
405.317 Revised	13637
405.318 Revised	13638
405.319 Revised	13638
405.320 Revised	13639
405.321 Added	13639
405.402 (g) added	17211
405.405 Heading revised; (d) removed	14093
405.406 (a) revised; (c), (d), and (e) added	6387
(e) corrected	7223, 7458
405.419 (c)(4) removed	14093
405.429 (b)(2) revised	14093
405.454 (k) added	6387
(a), (g), (h), and (k) revised	14093
405.502 (e) added	17212
405.603 Added	6387
405.622 Added	3598
405.1201—405.1230 (Subpart L) Revised	18978
405.1203 Added	23325
405.1204 Added	23325
405.1205 Added	23326
405.1206 Added	23326
405.1207 Added	23326
405.1208 Added	23326
405.1505 (g) added	3598

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20 CFR	39 FR Page
Chapter III	
405.116 (f) revised	32328
405.153 Revised	1750
405.214 (a) and (b) revised	2757
405.226 Added	2757
405.231 (h) and (l) revised	28624
405.232 (e) revised	28624
405.232a Added	28624
405.232b Added	28624
405.232c Added	28624
405.239 Revised	19483
405.240 (d) revised	19483
405.243 (b) example revised	19483
405.244 (c) revised	19483
405.245 Revised	19483
405.310 (i) revised	28625
405.313 Revised	1750
405.401—405.488 (Subpart D) Heading revised	34515
405.401 (a) revised	16883, 20164
405.402 (a) revised	16883, 20165
405.421 (e) revised	32328
405.451 (a) revised	16883
405.455 Added	16883
(d)(1) amended; (d)(2) revised	20165
405.460 Added	20165
405.461 Added	20166
(b)(3)(i) corrected	22415
405.490—405.499i Removed	34515
405.522 (a), (b) and (c) revised	32328
405.525 Revised	32329
405.601—405.685 (Subpart F) Heading revised	2239
405.601 Amended	2239
405.602 Amended	2239
405.604 Added	2239

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Chapter III—Continued

405.605 Revised.......... 2239
405.606 (b) revised; (c) added.......... 2240
405.607 Introductory text of (a) revised.......... 20167
405.613 (a) revised.......... 2240
405.614 (a) revised.......... 2240
405.615 (a) revised.......... 2240
405.616 Revised.......... 2240
405.685 (d) added.......... 2240
405.801 Revised.......... 12096
405.802 (b) through (f) revised.......... 12096
405.803 Revised.......... 12097
405.805—405.823 Revised.......... 12097
405.820 Revised.......... 12097
405.832 (d) redesignated as (e); new (d) added.......... 12098
405.841 Revised.......... 12098
405.842 (b) revised.......... 12098
405.902 (a) revised.......... 3933
405.904 (c) revised.......... 14589
405.905 Removed.......... 14589
405.911 (a) amended.......... 14589
405.913 (b), (c), and (d) revised.......... 14589
405.915 (b)(3) revised.......... 14590
405.916 Revised.......... 14590
405.921 (b) revised.......... 14590
405.927 (a) revised.......... 14590
405.929 Added.......... 14590
405.936 Revised.......... 14590
405.947 (b) revised.......... 14590
405.960 (a)(2) revised.......... 14590
405.964 Added.......... 14591
405.1001 Removed.......... 2251
405.1002 Removed.......... 2251
405.1003 Removed.......... 2251
405.1004 Removed.......... 2251
405.1005 Removed.......... 2251
405.1006 Removed.......... 2251
405.1007 Removed.......... 2251
405.1008 Removed.......... 2251
405.1009 Removed.......... 2251
405.1010 Removed.......... 2251
405.1035 (a), (d)(4) and (5), (e), (f), and (g) revised; (b) amended; (j) and (k) added.......... 41605
405.1101—405.1137 (Subpart K) Revised.......... 2240
405.1101 (f) revised.......... 35775
405.1121 (i) revised; (k) added; (l) redesignated from § 405.1122.......... 35775
405.1122 Redesignated as § 405.1121(l).......... 35775
Added.......... 35776
405.1124 Introductory text, (c), and (g) revised.......... 35776

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405.1126 Introductory text and (a) revised.......... 35777
405.1134 (j) revised.......... 35777
405.1137 (h) added.......... 35777
Introductory text and (a) through (e) revised; (i) added.......... 41607
405.1203 Removed.......... 2251
405.1204 Removed.......... 2251
405.1205 Removed.......... 2251
405.1206 Removed.......... 2251
405.1207 Removed.......... 2251
405.1208 Removed.......... 2251
405.1301 Removed.......... 2251
(b) (39 FR 2251) reinstated.......... 27795
405.1302 Removed.......... 2251
405.1303 Removed.......... 2251
405.1304 Removed.......... 2251
405.1305 Removed.......... 2251
405.1306 Removed.......... 2251
405.1307 Removed.......... 2251
405.1308 Removed.......... 2251
405.1309 Removed.......... 2251
405.1310—405.1317 (Subpart M) Revised.......... 33692
Effective date corrected.......... 36579
405.1310 Revised.......... 33692
405.1315 Revised.......... 33692
405.1401 Removed.......... 2251
405.1402 Removed.......... 2251
405.1403 Removed.......... 2251
405.1404 Removed.......... 2251
405.1405 Removed.......... 2251
405.1406 Removed.......... 2251
405.1407 Removed.......... 2251
405.1408 Removed.......... 2251
405.1409 Removed.......... 2251
405.1501 Revised.......... 2249
405.1502 Amended; (b)(2) revised.......... 2250
405.1503 Revised.......... 2250
405.1505 Revised.......... 2250
405.1510 Amended.......... 2250
405.1511 (b) revised.......... 2250
405.1513 Amended.......... 2250
405.1514 Amended.......... 2250
405.1515 Amended.......... 2250
405.1518 Amended.......... 2250
405.1519 Revised.......... 2250
405.1531 Revised.......... 2250
405.1532 Revised.......... 2250
405.1537 Amended.......... 2251
405.1542 (a) amended.......... 2250
(b) revised.......... 2251
405.1544 Revised.......... 2251

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Chapter III—Continued		39 FR Page
405.1545	Amended	2251
405.1550	Revised	2251
405.1560	Revised	2251
405.1563	Revised	2251
405.1590	Amended	2251
405.1591	Amended	2251
405.1627	(a)(3) revised	28625
405.1660	(a) and (c) revised	36470
405.1662	Revised	36470
405.1663	Revised	36470
405.1664	Introductory text and (d) revised	36470
405.1665	Introductory text revised	36470
405.1666	Revised	36471
405.1667	Revised	36471
405.1672	(a) and (b) revised	36471
405.1675	(a)(1) revised	3934
405.1680	Revised	3934
405.1692	Revised	36471
405.1693	Revised	36472
405.1694	Revised	36472
405.1801—405.1889	(Subpart R) Added	34515
405.1901—405.1910	(Subpart T) Added	2251
	Redesignated as Subpart S	11419
405.1911	Added	35777

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Chapter III		40 FR Page
405.102	Revised	24357
405.103	Revised	24358
405.104	Revised	24358
405.105	Added	24359
405.106	Added	24359
405.116	(g) revised	17747
405.120	(a)(1) amended; (d) revised	23289
405.126	Revised	43896
405.127	Revised	43897
405.128	Revised	43898
	Corrected	46309
405.128a	Added	43898
405.129	Removed	1023
405.195	Added	1023
405.196	Added	1023
405.201—405.252	(Subpart B) Appendix added	17747
405.205	Revised	18165
405.210	Revised	18166
405.213	Text designated as (a); (b) added	18166
405.214	(d) added	18166
405.217	(b) introductory text and (c)(1) revised; (g) through (i) added	43211
405.221	(e) added	18166
405.222	(c) revised	43212
405.223	(e) added	18166
	(c) revised	43212
405.230	(a)(2) and (5) revised	44321
405.231	(g) and (h) revised	17747
	(l) revised; (m) added	44321
405.232	(e) revised; (j) added	44321
405.236	(b) revised	44321
405.239	Revised	44322
405.250	(b)(3) revised	44322
405.250a	Added	44322
405.301	Revised	1023
405.310	Introductory text revised	1023
	Introductory text (m) and (n) added	24360
405.315a	Added	36314
405.315b	Added	36315
405.330	Added	1024
405.331	Added	1024
405.332	Added	1024
405.402	(c) introductory text revised	32743
	(c)(9) added	33440
405.415	(k) added	32743
405.419	(e) added	32743
405.429	(b)(3) added	32743
405.430	(a), (c)(1), (d)(1) and (2), and heading of (e)(1) revised	22540
405.432	Added	5761
405.433	Added; eff. 4-26-76	34513
405.435	Added	32742
405.454	(j) added	29816
405.460	(e) revised	32744
405.465	Added	33440
405.466	Added	33443
405.502	(a) revised	25447
405.504	(a) revised	25447
405.512	Added	7639
405.521	(d) redesignated as (d)(1); (d)(2) and (3) added	33443
405.614	(a)(4) and (c) revised; (a)(5) added	36315
405.702	Revised	1024
405.704	Revised	1025
405.705	(e) added	53386
405.708	Revised	1025
405.710	Revised	1025
405.714	Revised	1025

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Chapter III—Continued

405.715 Revised........1025
405.716 Revised........1025, 53387
405.717 Revised........1025, 53387
405.718—405.718e Added........53387
405.720 Revised........1025
405.722 Revised........1026
405.730 Revised........1026, 53387
405.740 (h) added........1026
405.745 Revised........1026
405.803 (b) revised........1026
405.820 (b)(4) added........1026
405.902 (b) introductory text and (b)(1) and (2) revised; example 4 added........18166
405.912 (b) revised........11865
405.1021 (i)(3) removed; (j) added........24324
405.1022 (b) revised........26656
405.1035 Effective date postponed........14592
(e)(6)(ii) amended........14592
(e) and (f) effective date postponed........28052, 33033, 42006
405.1121 Introductory text and (f) revised........24325
405.1137 Effective date postponed........14592
(d)(2) amended........14592
405.1221 (i) added........24325
(a) and (h) revised........56661
405.1310 (a) and (d) revised........3765
405.1315 (c)(3) revised........3766
405.1501—405.1595 (Subpart O) Heading revised........36315
405.1501 Heading, (a) and (b) revised; (f) added........36315
405.1502 (e) added........36316
405.1503 Revised........36316
405.1504 Revised........36316
405.1505 Introductory text and (k) added........36316
405.1519 Revised........36316
405.1530 Revised........36316
405.1531 Revised........36316
405.1532 Revised........36316
405.1534 Revised........36316
405.1536 Revised........36317
405.1537 Revised........36317
405.1542 (a) revised........36317
405.1543 Revised........36317
405.1545 Revised........36317
405.1550 Revised........36317
405.1551 Revised........36317
405.1552 Revised........36318

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405 Effective date corrected........41912
405.133 Added........21341
(a) corrected........22560
405.165 Revised........21344
405.170 (b)(3) and (4) revised; (c) added........21344
405.232 (e)(2)(iii) revised........20871
405.251 (b)(4)(ii) and (iii) revised; (b)(4)(iv) added........1492
405.350 Revised........1492
405.352 Introductory text revised........1492
405.355 Revised........1492
405.371 (c) revised........52050
405.402 (g) revised........49594
405.419 (a) and (b)(2)(iii) revised........52050
405.429 Revised........46292
405.432 (f)(3) added........49594
405.433 Effective date extended to 8-26-76........16968
(c) revised........49594
405.454 (l) added........52050
405.455 (a) revised........49594
405.460 (f)(5) added........49595
405.502 (e) revised........49595
405.607 (a)(3) revised; (a)(4) added........1492
405.711 Revised........47917
405.717 Revised........47917
405.718a (b)(1) and (3) revised........47917
405.722 Revised........47917
Nomenclature change........51588
405.730 Nomenclature change........51588
405.740 Nomenclature change........51588
405.741 Nomenclature change........51588
405.747 Nomenclature change........51588
405.750 Nomenclature change........51588
405.1024 (b) amended........27962
405.1031 Introductory text revised........22509
405.1201—405.1230 (Subpart L) Appendix amended........17893
405.1230 Revised........20871
405.1310 (m) added........22510
405.1314 (b)(13) added........22510
405.1317 (b)(8) added........22510
405.1501—405.1595 (Subpart O) Heading revised........8481
405.1501 Heading, (a) and (c) revised........8481
405.1502 (b) revised........8482
405.1503 Revised........8482

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405.1505 (a) revised....8482
405.1510 Revised....8482
405.1511 (a) revised....8482
(b) revised....47918
405.1512 Revised....8482
405.1513 Revised....8482
405.1515 Revised....8482
405.1516 Revised....8483
405.1519 Revised....8483
405.1520 Revised....8483
405.1530 Revised....8483
405.1531 Revised....8483
(a) revised....47918
405.1532 Revised....8483
405.1534 Revised....8483
405.1536 Revised....8483
405.1537 Revised....8484
405.1542 (a) revised....8484
405.1543 Revised....8484
405.1545 Revised....8484
405.1550 Revised....8484
405.1551 Revised....8484
405.1552 Revised....8485
405.1556 Revised....54753
405.1562 (a) revised....54753
405.1632 (a) and (c) revised....21344
405.1633 (a)(2) and (b) revised....21345
405.1701—405.1737 (Subpart Q) Heading and text revised....20865
405.1845 (d) revised....52051
405.1871 (b) revised....52051
405.1875 Revised....52051
405.1877 Revised....52051
405.1901 (c) and (d) redesignated as (d) and (e); new (c) added....22510
405.1910 (c) amended....27962
405.1912 Added....22510
405.2040 Added....49595

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405.2041 Added....49595
(d) corrected....53320
405.2042 Added....49596
(c)(2) corrected....53320
405.2043 Added....49598
(e) table corrected....53320
405.2044 Added....49600
405.2045 Added....49600
405.2046 Added....49601
405.2047 Added....49601
405.2049—405.2053 Added....49602
405.2054 Added....49604
(c) corrected....53320
405.2059 (c) and (j) revised....47918
405.2060 (d) revised....47918
405.2065—405.2092 Added....39308
405.2100—405.2171 (Subpart U) Added....22511

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Chapter III

405 Redesignated as 42 CFR 405....52826
405.415 (d)(1), (2), and (3) headings added, (d)(3) existing text designated as (d)(3)(i) and heading added; (d)(3)(ii) added....45897
405.504 (a)(2) and (3)(i) and (ii) revised....18275
405.1035 (l) added....1029
405.1625—405.1697 (Subpart P) Heading revised....44220
405.1695 Added....44220
405.1696 Added....44220
405.1697 Added....44220

Table 2—45 CFR Parts 246 and 248 Through 252 List of CFR Sections Affected for 1973 to 1977

NOTE: At 42 FR 52827, September 30, 1977, regulations formerly appearing in Title 45 as Parts 246, 248, 249, 250, 251 and 252 were redesignated and transferred into Title 42 as Parts 446, 448, 449, 450, 451 and 452, respectively.

The following list of CFR sections affected contained in this table formerly appeared in Title 45 and is updated through September 30, 1977.

1973

45 CFR

	38 FR Page
Chapter II	
248.10 (a)(1), (b)(2)(ii) and (iv), and (d)(1) and (2) revised; (b)(3) and (4) redesignated as (b)(5) and (6); (b)(5) redesignated as (b)(7) and revised; new (b)(3) and (4) added	33380
248.21 (a) revised; (b) redesignated as (c) and revised; new (b) added	33382
248.30 (b)(1) revised	33382
248.50 Revised	30259
248.60 (a)(1), (2), and (3)(iv) revised	33383
Effective date corrected	31174
249.10 (b)(4)(i) heading and introductory text revised	12112
249.33 (a)(1)(vii) and (c)(2) revised	21413
249.81 Revised	33383
252.10 (b)(1), (c)(2)(iii), and (d) revised	12112
252.20 Removed	12113

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	39 FR Page
Chapter II	
248.1 Added	9513
248.2 Added	9515
248.3 Added	9516
(b)(5) and (c)(2)(i) and (ii) amended	36590
248.4 Added	9517

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	39 FR Page
Chapter II—Continued	
248.10 Introductory text added	9518
(b)(4) revised	16971
248.11 Existing text designated as (b); (a) added	9518
248.21 (a) revised	5552
Introductory text added	9518
(a)(3)(ii)(A) and (B) amended	36590
248.30 Revised	9518
248.50 Revised	9518
248.60 (a)(1) revised; (b)(9) and (10) added	2221
248.70 Revised	9518
248.80 Revised	9518
(c) corrected	10253
249.10 (b)(14) and (c) revised; (b)(15) redesignated as (b)(17), new (b)(15) added; (b)(16) reserved; (d)(1)(iv), (v), and (vi) added	2221
(b)(4)(i) revised	2257
(b)(15)(i)(*e*), (ii) introductory text, (ii)(*a*), (iii)(*b*) and (d)(1)(vi) corrected	8918
(a)(1), (2), (5), and (6) and (b)(7), (11), and (17) revised; (a)(9) removed; new (a)(9) and (10) added	16971
(a)(3) revised	27906
(b)(6) revised	37637
(b)(4)(i)(B) revised; (b)(15)(vi) added	40019
(b)(1) and (14)(i)(A) revised	41611
249.11 Redesignated as 249.20	2223
249.12 Added	2223

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Chapter II—Continued
(a)(1)(ii)(B) and (9)(iii) and (c)(2) and (3)(v) corrected.........8918
249.13 Added..........2226
(c)(6)(ii)(C)(*1*) and (12)(ii)(E) corrected; (h)(i) through (x) correctly designated as (h)(1) through (10); (h)(10) revised..........8918
249.20 Redesignated from 249.11 and revised..........2223
249.31 Added..........12866
249.32 Revised..........16972
249.33 Revised..........2254
(a)(1)(i), (iii), (2), (4)(iii)(B), and (8)(i)(B) corrected..........8918
(a)(3)(i) revised..........16972
(a)(1) amended..........41611
249.40 Revised..........5553
(a)(2) and (b) revised..........36590
(a)(2)(ii) table corrected..........39267
249.41 Revised..........16972
250.18 Added..........41611
250.19 Added..........41612
250.20 Amended; (a)(3) added.....35778
Revised..........41617
250.23 Amended..........41618
(a)(1)(ii) revised; (b)(2) removed; (b)(1) redesignated as (b); (c) added..........41618
250.24 Added..........2234
(a)(1) and (3)(v)(B) corrected...... 8918
(a)(1)(ii) revised..........41618
250.30 (a)(6) revised; (b)(3)(iii) added..........2235
(b) and (d) revised..........21135
(a) (2) through (7) redesignated as (a) (3) through (8); new (a)(2) added; (b) introductory text and (b)(1) revised..........28288
(b) revised..........31639
(b) and (d) revised..........43632
250.70 Added..........16973
250.80 Revised..........7930
250.90 Added..........17763
(b)(2)(ii) corrected..........22269
250.100 Added..........2256
250.120 Revised..........16973
(d) amended..........36590
250.220 (Subpart C) Added..........31528
(b)(4) corrected..........32739

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Chapter II
248.1 (a)(3) added; (b)(3) revised..........52020
248.10 (b)(3) revised..........52020
248.70 (a)(2) and (3) and (c)(1) revised..........25819
249.10 (b)(1) and (14) effective date stayed..........14597
(c)(3) removed; (c)(4) added....... 28793
(b)(4)(i) revised..........43901
249.33 (a)(1)(i) effective date stayed..........14597
(a)(7) removed..........28793
249.82 Revised..........20517
250.18 Effective date stayed........14597
(a)(1)(iii) revised..........30819
250.19 Effective date stayed........14597
(a) amended..........14597
(a)(1)(viii) effective date postponed.................28071, 33033, 33036
(c) added..........30819
249.20 Revised..........52020
250.23 Effective date stayed........14597
250.24 (a)(1)(ii) effective date stayed..........14597
250.25 Added..........27221
250.30 (b)(3)(iii) revised... 14598, 15388
(b)(2) revised..........34519
(d) revised..........52021
(b)(2)(ii) revised..........54000

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Chapter II
248.1(c)(iv) revised..........22055
248.10 (b)(2)(iv) revised..........22055
248.60 (a)(2) and (a)(3)(iv) revised..........22055
249.10 (b)(16) added (c)(1) and (2) revised; (c)(5) added............ 2198
(a)(6)(iii) revised..........22055
(a)(4) and (b)(7) revised; eff. 11-23-76..........35848
249.12 (a)(1)(ii) and (c)(6) revised..........12884
249.13 Introductory text revised..........12885
249.31 Revised; eff. 10-26-76.......36208
250.18 (f) redesignated from 250.20(b)(2) and revised..........23673
250.20 (b)(2) revised and redesignated as 250.18(f)..........23673

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250.23 Revised.................................. 2200
(a)(1) introductory text, (i), and (iv) amended.............................22055
250.30 (b)(3)(ii) revised.................. 2201
Eff. date extended to 8-26-76.... 16968
(a) (3) through (8) redesignated and revised as (a) (4) through (9); new (a)(3) added................ 27305
(b) amended.................................. 27307
(a)(2)(i) and (iii) and (b)(1) revised... 51402
(a)(3)(iii)(B)(*1*) and (*4*), (a)(3)(iv) introductory text and (A) amended...................... 53994
250.80 (a)(5) revised...................... 13585
(a)(4) revised; (b) redesignated as (c); new (b) added................ 26221
250.210 Added; interim rule effective date 12-31-72................ 48738

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Chapter II

246 Redesignated as 42 CFR Part 446...................................... 52827
246.160 Added.................................. 33293
248 Redesignated as 42 CFR Part 448...................................... 52827
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NOTE: At 42 FR 52826, September 30, 1977, regulations formerly appearing in Title 42 as Part 101 were redesignated and transferred into Parts 460 through 480 of this title.

The following list of CFR sections affected contained in this table formerly appeared in Title 42 (1 to 399) and is updated through September 30, 1977.

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(No regulations published)

1974

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101.37 Amended	23060
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1975

(No regulations published)

1976

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List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations which were made by documents published in the FEDERAL REGISTER since January 1, 1973, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters and parts as well as sections for revisions.

For the period before January 1, 1973, see the "List of CFR Sections Affected, 1949-1963, and 1964-1972," published in three separate volumes.

For a complete "List of CFR Sections Affected" before the recodification at 42 FR 52826, September 30, 1977, see Tables 1, 2 and 3.

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(No regulations published)

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(No regulations published)

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(No regulations published)

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405.607 Introductory text revised; (c) added 41642
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